

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

LARRY G. JUNKER,

Plaintiff,

v.

MEDICAL COMPONENTS, INC., et al.,

Defendants.

CIVIL ACTION

No. 13-4606

Goldberg, J.

January 14, 2021

MEMORANDUM OPINION

This case involves a dispute over a design patent for a medical device used to insert a catheter into a patient’s vein. Plaintiff Larry Junker owns the patent at issue, United States Design Patent Number D450,839 (the “D’839 Patent”), for the handle design of what is referred to as an “introducer sheath.” Plaintiff has sued Defendants Medical Components, Inc. and Martech Medical Products, Inc., alleging that their products, the Super Sheath, Super Sheath 2.0, the Super Sheath Valved Tearaway, and the Super Sheath Valved Tearaway 2.0 (the “Accused Products”) infringe the D’839 Patent. Defendants counter that the D’839 Patent is invalid.

I held a bench trial from January 27, 2020 to January 31, 2020, wherein evidence of infringement, invalidity, and damages was presented. After careful consideration of the entire record, and for the following reasons, I find that Plaintiff has demonstrated, by a preponderance of the evidence, that the Accused Products infringe the D’839 Patent. I also conclude that Defendants have failed to prove, by clear and convincing evidence, that the D’839 Patent is invalid because of

incorrect or incomplete inventorship, inequitable conduct, anticipation, obviousness, and a primarily functional design. I award Plaintiff \$1,247,910 in disgorged profits.

This Opinion sets forth my findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(a).

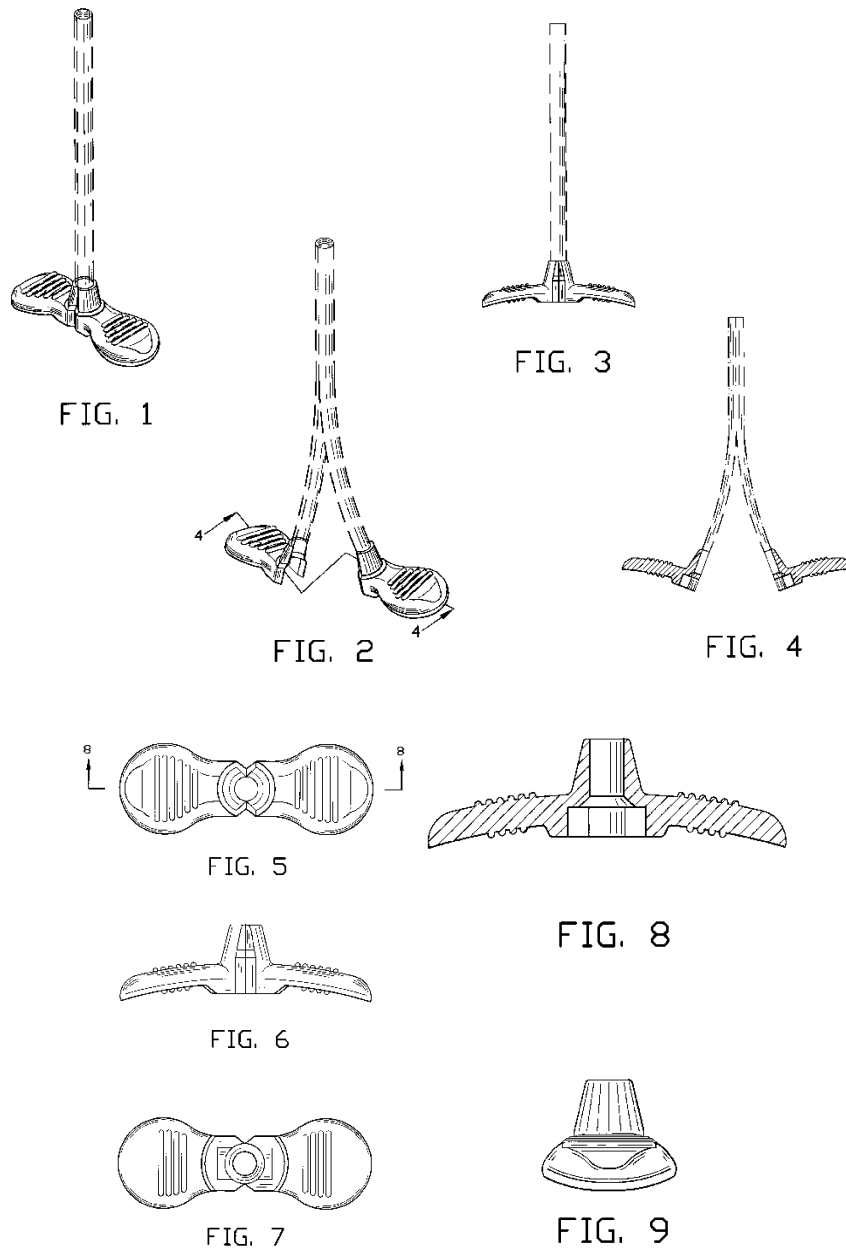
I. FINDINGS OF FACT

1. The design patent at issue in this case is for the handle of a medical device called an introducer used to insert a catheter into the vein of a patient. (See N.T., Vol. 1, 56:9–57:12, 75:2–77:11.) Generally, a doctor using this device first punctures the patient’s vein with a needle attached to a syringe, using the syringe to aspirate blood. Once the syringe is filled with blood, the doctor feeds a guidewire through the needle into the vein. The needle is withdrawn, leaving the guidewire in place, allowing the doctor to insert the opposite end of the guidewire into the introducer’s sheath. The guidewire guides the introducer’s sheath into the vein and is removed. The doctor then feeds a dilator with a sharp point through the introducer’s sheath, allowing the doctor to spread the vein’s tissue and facilitate insertion of a catheter tube. A catheter tube is fed through the introducer’s sheath into the vein. The doctor then removes the introducer by breaking the handles in half and tearing the sheath away from the catheter tube like a banana peel, leaving the catheter in place.

A. The Patent

2. Plaintiff is the owner and named inventor of the D’839 Patent, entitled “Handle for Introducer Sheath,” applied for on February 7, 2000 and issued by the United States Patent and Trademark Office (“PTO”) on November 20, 2001. (Pl.’s Ex. 1.) The D’839 Patent contains a single claim: “The ornamental design for a handle for introducer sheath, as shown and described.” (Id. at 1.) Included with the D’839 Patent are nine Figures, shown below, which depict the claimed

design from different perspectives, including from the front, the side, the top, the bottom, and a cross-sectional view. (Id.)



(Id.)

3. In my October 31, 2017 Claim Construction Order, I construed the D’839 Patent’s single claim as follows: “The D’839 Patent claims the ornamental design of a handle for an

introducer sheath, as shown in Figures 1–9. The broken lines in the Figures of the D’839 Patent represent unclaimed subject matter.” (ECF No. 192.)

B. The Parties

4. Plaintiff, who has a bachelor’s degree in biology and a minor degree in chemistry, began his career in the field of medical devices in 1975 as a pacemaker salesman. (N.T., Vol. 1, 67:7–68:23.) From 1975 to 1978, Plaintiff witnessed over 3,000 pacemaker implant procedures and over 550 catheter implant procedures. (*Id.* at 69:3–7.) At the end of the 1970s, Plaintiff started his own company, Medical Life Systems, which purchased and resold pacemakers, catheters, and catheter insertion kits. (*Id.* at 70:7–72:9.) Eventually, Plaintiff’s company began making the catheter insertion kits itself, which generally included a needle, syringe, guidewire, and introducer. (*Id.* at 71:15–17.) The main item in these kits was the introducer. (*Id.* at 72:10–17.) Plaintiff’s company also designed and manufactured some of the components sold in the catheter kits, including an introducer sheath. (*Id.* 73:23–24; N.T., Vol. 2, 5:19–6:8.) The introducer sheath that Plaintiff’s company manufactured had very small handles and was not like the claimed design that Plaintiff later conceived in the mid-1990s. (N.T., Vol. 2, 5:19–6:8.) Plaintiff was involved in the business of making and selling catheter insertion kits until approximately 2001. (*Id.* at 73:18–19.)

5. Apart from the D’839 Patent, the only patent at issue in this matter, Plaintiff has another patent for a medical device used in the insertion of catheters. Plaintiff is a named co-inventor, along with John Thorniley, on United States Patent No. 6,645,178, “Apparatus for Inserting Medical Device,” applied for on November 25, 1998 (before the D’839 Patent) and issued by the PTO on November 11, 2003 (the “’178 Patent”). (Pl.’s Ex. 55.) This utility patent claims a “transition[less] sheath” that, instead of using a dilator, uses an “obturator.” (N.T., Vol. 1, 90:24–91:14.) The ’178 Patent’s specification describes the invention as:

an apparatus . . . for inserting a medical device such as a catheter into a patient. The apparatus comprises a rigid obturator defining a distal obturator end. A flexible sheath has an internal bore terminating at a distal sheath end. The internal bore of the sheath receives the obturator for supporting the sheath to enable insertion for the sheath within the patient. The obturator is advanced relative to the sheath to fracture the distal sheath end. The obturator is removed from the sheath for enabling the medical device to be inserted through the sheath to enter into the patient. The sheath is removed from the patient while the medical device remains within the patient.

(Pl.’s Ex. 55, Abstract.) Figures 14A and 15A of the ’178 Patent, although a utility patent, depict, as shown below, a propeller-shaped handle with large, oblong or oval, rounded tabs, the underside of which has ribs. (*Id.*)



6. Defendants, Medical Components, Inc. and Martech Medical, Inc. (individually, “MedComp” and “Martech,” respectively), are “sister” companies with common ownership. (N.T., Vol. 5, 67:24-68:4.) Despite this common ownership, Defendants are separate entities, with separate “systems” and addresses. (*Id.* at 68:11–15.) MedComp designs and develops products, has them manufactured, and then sells them to the end user. (*Id.* at 67:7–14.) MedComp primarily sells dialysis catheters, which make up more than fifty percent of its sales, as well as other vascular access devices. (*Id.* at 66:11–23.) Martech is an original equipment manufacturer and a “contract” manufacturer. (*Id.* at 67:15–17.) Most of Martech’s business is “contract” manufacturing, where “someone will come to [Martech] with an idea . . . [a]nd since [Martech is] full service, [Martech] take[s] that idea . . . and [Martech will] develop it the whole way. [Martech can] even package it .

...” (Id. at 67:17–23.) Martech sells a broader array of products, including pacemakers, feeding tubes, and “pretty much everything that isn’t bone fixation or neurology.” (Id. at 66:24–67:3.)

C. Evidence Pertaining to the Invention of the Claimed Design

7. Based on his experience in observing catheter implant procedures and the anecdotal evidence that he gathered in speaking with the doctors who performed those procedures, Plaintiff sought to improve the introducer sheath design. (N.T., Vol. 1, 87:18–88:5, 91:20–93:10.) Conceptually, he started developing the claimed design in 1986, but “it wasn’t until ’96, ’97 that [he] decided [he] was going to find someone to make [him] a prototype and to make some drawings for [him.]” (N.T., Vol. 1, 87:18–13, 91:11–19.) In that timeframe, Plaintiff conceived an introducer sheath handle design, which included (1) a “funnel entrance,” (2) a hub with notches in either side, (3) a smoother transition or better taper on the tip, where the dilator meets the sheath, (4) a lubricious coating, and (5) larger, “bulbous” ears on the handle that were upswept and rounded-off at the ends. (Id. at 91:23–93:6; N.T., Vol. 2, 13:18–14:19.)

8. By inventing the claimed design, Plaintiff was trying to accomplish an “improved appearance” that would be “more appealing” and “easier to sell.” (N.T., Vol. 2, 5:3–17.) Plaintiff believed his improved design would be “eye catching” to customers, since it was so different from the other introducer handle designs on the market. (Id.) In addition, because of the larger ears or tabs of Plaintiff’s design, a doctor using the device could better grasp the handle, and the rounded edges of the handle would help the doctor avoid tearing or snagging his gloves when peeling away the introducer sheath from the catheter tube. (Id. at 13:18–14:19.)

9. Although Plaintiff conceived a new introducer handle design, he could not draw the design himself and needed the right machinery to manufacture the product. (N.T., Vol. 2, 6:12–21.)

10. As a result, in 1997, Plaintiff contacted a company, Prepco, to manufacture Plaintiff's new "peel-away" introducer sheath handle design. (Id. at 6:22–7:15.) He also intended to have Prepco manufacture the sheath and dilator and planned to purchase the product embodying his design from Prepco in "bulk non-sterile" and sell the introducers in his company's kits. (Id. at 9:7–11.)

11. Plaintiff visited Prepco's facilities in Canada on a couple of occasions. (Id. at 8:3–8.) Prepco created some drawings for Plaintiff at Plaintiff's direction (see Defs.' Ex. 17(I)) and made a prototype of his handle design from those drawings. (N.T., Vol. 2, 6:22–7:15, 8:3–8.) However, the prototype design did not meet Plaintiff's criteria. (Id. at 8:9–21.) It needed more refinement, as it was "just a concept type thing" that represented Plaintiff's "general vision." (Id.; see also id. at 16:15.)

12. Plaintiff intended to continue working with Prepco to refine the prototype of his introducer sheath design, but his relationship with Prepco did not continue after Plaintiff met with James Eddings.

13. Plaintiff knew James Eddings, the founder of Galt Medical and Xentek Medical, because he had purchased bulk, non-sterile guidewires from Eddings's other company, Argon Medical, that Plaintiff included in his catheter insertion kits. (Id. at 9:12–24; N.T., Vol. 4, 9:23–10:4.) In addition to guidewires, Eddings also manufactured a "hemostasis valve type introducer," which is a different kind of product than the "peel-away" introducer sheath. (Id. at 10:2–8.) Plaintiff had visited Eddings facilities a few times over the years and would see him at trade shows. (Id. at 10:11–14.)

14. On August 13, 1998, Eddings called Plaintiff and asked if he could "come by" Plaintiff's facility in Florida. (Id. at 12:22–24.) During this visit, Plaintiff mentioned to Eddings

that he was developing a new introducer sheath product. (Id. at 12:24–13:1.) Eddings joined Plaintiff at his home for dinner, after which the two discussed Plaintiff’s introducer sheath design. (Id. at 13:3–15:1.) Before doing so, Plaintiff asked Eddings to sign a non-disclosure agreement (“NDA”), which Eddings executed on behalf of Galt Medical and Plaintiff executed on behalf of his company at the time, Medical Life Systems. (Id. at 11:11–12:9; N.T., Vol. 4, 67:12–72:8; Pl.’s Ex. 7.) Once the NDA was signed, Plaintiff told Eddings about the features of the introducer handle design that he had conceived and was working toward manufacturing. (N.T., Vol. 2, 13:16–14:19.)

15. At the time of this meeting, Eddings and Galt Medical did not have a “peel-away” introducer sheath in production, and Xentek had not yet been formed. (Id. at 67:18–22.)

16. Also, at this meeting, Plaintiff told Eddings about his work with Prepco, to which Eddings expressed interest in visiting Prepco’s facility with Plaintiff. (Id. at 15:3–14.)

17. Approximately one month after the August 1998 meeting, Eddings, who had sent one of his employees with Plaintiff to visit Prepco’s facility, called Plaintiff and told him that Prepco could not make his product but that Eddings’s company, Galt Medical, could. (Id. at 15:3–21:12.)

18. In November 1998, Plaintiff, who was in Dallas, Texas for a trade show, was invited to meet with Eddings and his colleagues at Galt Medical’s facility to discuss Plaintiff’s new introducer sheath design. (Id. at 21:13–6, 23:15–24:3.)

19. Before that meeting, in September 1998, Eddings had started a new company, Xentek Medical, which, according to Eddings, was formed to develop, manufacture, and sell a tearaway introducer product. (N.T., Vol. 4, 60:21–24, 61:9–62:4.)

20. Eddings himself had only an architecture degree and no prior experience in manufacturing tearaway introducer sheath products. (N.T., Vol. 4, 6:24–7:2, 60:25–61:8.) Eddings

had hired an engineer named Richard Gillespie to research, design, develop, and oversee the manufacture of the tearaway introducer sheath product. (N.T., Vol. 4, 19:15–20:2, 22:3–8.)

21. Gillespie had owned a company called Vanguard Medical Engineering, which he sold to Eddings in 1998 and which was later consolidated with Xentek. (Gillespie Tr. Dep., 17:3–5, 17:16–18:2.) Gillespie became a vice president at Xentek, and he also managed Xentek’s Athens, Texas facility. (Id. at 18:4–5, 20:12–20.)

22. Plaintiff toured Xentek’s facility when he went to Dallas in November 1998. According to Plaintiff, there were no projects in progress, save a couple of guidewire winding machines, which were not working. (N.T., Vol. 2, 22:10–23:14.) Neither Xentek nor Galt Medical had the capability, i.e. the molding equipment, to make an introducer sheath product. (N.T., Vol. 4, 61:19–20, 62:12–63:22.)

23. Eddings had told Plaintiff that Gillespie had drafting experience and that Plaintiff should come meet Gillespie and Eddings in Texas so that Gillespie could provide Plaintiff with accurate drawings of his design. (N.T., Vol. 2, 23:15–24:3.) Plaintiff was not shown any drawings by Eddings, Gillespie, or anyone else before or at the November 12, 1998 meeting. (Id. at 24:4–7, 39:24–40:9.)

24. Gillespie had, in fact, created two introducer sheath design sketches, dated November 9, 1998, at Eddings’s direction. (Gillespie Tr. Dep. 52:4–56:8; Defs.’ Exs. 17(G), 17(H).) These sketches depicted the basic outline of an introducer sheath with a rectangular handle and slightly tapered, rounded-off tabs. (Defs.’ Exs. 17(G), 17(H).)

25. Eddings never informed Plaintiff that he had been working on a design of the introducer sheath handle or had even thought about such a design. (N.T., Vol. 2, 39:24–40:9.) And

neither Eddings nor Gillespie mentioned the November 9, 1998 sketches at the meeting with Plaintiff a few days later. (Id.)

26. Gillespie, who is trained in mechanical engineering, had no experience designing tearaway introducer sheath handles prior to being hired by Xentek. (Gillespie Tr. Dep., 180:1–6.) Gillespie also had no prior experience with design patents or “aesthetic design.” (Id. at 218:19–22.)

27. Gillespie relied on Eddings’s input as well as other existing introducer sheath products to create the November 9, 1998 preliminary sketches. (Gillespie Tr. Dep., 56:6–16, 195:10–14.) Eddings also provided Gillespie with guidance about “the look and aesthetics” of “the tear-away introducer hub” and directed all aspects of the design throughout the development process. (Id. at 32:13–22, 42:6–8.) Eddings gave Gillespie input regarding “what the design from an overarching standpoint was to achieve” as well as “specific guidance about certain quality attributes that he felt w[ere] important . . . to try to attain in [their] design effort” (Id. at 32:13–22.)

28. Gillespie admitted that Eddings may have been influenced by others outside of the company with regard to what features he thought were important or desirable for the introducer sheath product. (Id. at 45–46.)

29. On November 12, 1998, Plaintiff, Eddings, and Gillespie met at Galt Medical to discuss the tearaway introducer sheath product. (See Defs.’ Ex. 17(E).) Gillespie was unaware of any meetings that Eddings had with Plaintiff before Xentek was formed and before he first met Plaintiff at the November 1998 meeting. (Gillespie Tr. Dep., 183:4–9, 243:14–17; Pl.’s Pretrial Memo., Stipulation No. 5, at 7.) Gillespie was also not aware of the NDA that Plaintiff and Eddings had signed in August 1998. (Gillespie Tr. Dep., 180:19–181:6.)

30. The November 12, 1998 meeting was memorialized in a memorandum prepared by Gillespie. (Defs.’ Ex. 17(E).) This memorandum, dated December 4, 1998, which Gillespie sent to Plaintiff, “was taken directly and derived directly from [Gillespie’s] handwritten notes” and only Gillespie contributed to the content of this memorandum. (Gillespie Tr. Dep., 87:2–20.)

31. Plaintiff told Gillespie and Eddings at this meeting about his introducer sheath design: “I went into the background of why it was important. Why I thought it was important. What the doctors felt about it. And I had kind of a shopping list of . . . features that I wanted to see in this new design. So I went down one by one [] all of the features And pointed out some that were more important than . . . maybe others.” (N.T., Vol. 2, 24:8–16.)

32. Gillespie’s December 4, 1998 memorandum reflects that, apart from a handful of specific references, a majority of the discussion of the desirable attributes of the introducer sheath product are not attributed to any one individual at the meeting. (Defs.’ Ex. 17(E).) For instance, the memorandum states, “[s]heath hub is to have a ‘funneled entrance’ on the proximal end for ease of introduction of Dilator and other devices.” (*Id.* at 2.) Although “‘funneled entrance’” is enclosed in quotation marks in the memorandum, it is not attributed to any one speaker. (*Id.*)

33. One of the few ideas memorialized in Gillespie’s memorandum that is linked to a specific person is related to the introducer sheath handle. (*Id.*) The memorandum states, “[t]he handle size is important. [Plaintiff] showed a [sic] SLA prototype of a ‘preferred embodiment’ of sheath/dilator set.” (*Id.*)

34. Gillespie attributed this comment about handle size to Plaintiff and acknowledged that Plaintiff had brought an SLA prototype to the meeting and used that prototype to note the importance of the handle size and that the ears or tabs should be larger. (Gillespie Tr. Dep., 91:21–

92:2, 97:18–21, 99:12–20, 102:14–17.) Gillespie characterized this contribution as a “design consideration.” (*Id.* at 97:18–21, 104:1–4.)

35. Gillespie’s memorandum also states that, at this meeting, Eddings announced that Xentek “would reserve the right to make the final determination of the Sheath and Dilator hub shape and configuration for this would be a proprietary product of Xentek, not a ‘make to order’ product” and that Gillespie would be “project leader.” (Defs.’ Ex. 17(E) at 2, 4.)


36. After the November 12, 1998 meeting, Gillespie sent Plaintiff a fax, requesting “[s]everal things which would be of great help” for “our Tear-away Sheath & Dilator product development program,” including a prior art patent, various sample products, a list of procedures for which the product was intended, and a list of the other products that the introducer sheath was “to cooperate with in use.” (Defs.’ Ex. 17(L).)

37. Plaintiff provided Gillespie with this information and soon after received from Gillespie the November 9, 1998 design sketches, referenced in ¶ 24 *supra*. (N.T., Vol. 2, 31:13–32:10.) Again, until then, Plaintiff was unaware of these sketches and had never seen them. These sketches did not depict the “Mickey Mouse ear” handle shape of Plaintiff’s design that he had disclosed at the November 12, 1998 meeting: “the big thing[] is that the handles were not anywhere close to what I had described to him that I needed.” (*Id.* at 32:11–18.)

38. Galt Medical also sent Plaintiff a prototype or “SLA rendition” of the introducer sheath handle because Plaintiff thought Eddings wanted his opinion. (*Id.* at 32:22–25, 33:18–19; Pl.’s Ex. 9.)

39. The prototype did not look like the design that Plaintiff wanted, and Plaintiff relayed his critiques to Eddings in a fax dated December 16, 1998, stating that he liked certain aspects of the prototype but “would really like to see *larger (wider) handles* [because] [t]he

prospective customer seemed to like this design.” (N.T., Vol. 2, 33:1–3; Pl.’s Ex. 11 (emphasis added).) Plaintiff also included in the fax a rough sketch, as shown below, of the type of handle shape he desired:

3. I would really like to see larger (wider) handles.  The prospective customer seemed to like this design.

(Pl.’s Ex. 11.)

40. The prototype sent to Plaintiff by Galt Medical did not have the same ear shape as the final product and, after Plaintiff sent the fax to Eddings, Eddings directed Gillespie to change the design and enlarge the “ears.” (Gillespie Tr. Dep., 198:12–17, 205:5–21.) Eddings never told Gillespie that this change was suggested by Plaintiff. (*Id.* at 205:22–24, 206:2–21.)

41. Gillespie characterized the sketch in Plaintiff’s fax as “a general representation of the bulbous shape of the hubs” and a general description and sketch of the desired handle shape. (*Id.* at 113:1–13.) Gillespie also stated that the “Mickey Mouse” ear shape of the handles was a “significant departure” from prior introducer sheath handle designs because most of the prior handles were rectangular. (*Id.* at 271:15–22.)

42. On August 6, 1999, Gillespie drew a “subassembly drawing” of the introducer sheath product, which would be used to construct the injection mold to create the tearaway-sheath component. (*Id.* at 116:19–21; Defs.’ Ex. 17(N).) This drawing was created during a one-on-one meeting between Gillespie and Eddings. (Gillespie Tr. Dep., 132:2–133:13.)

43. Gillespie claimed that he and Eddings were responsible for all aspects of the introducer sheath design depicted in this drawing, except the “propeller shape” of the tabs “approximated in the final design,” which Gillespie attributed to Plaintiff. (*Id.* at 133:22–25.)

44. For the reasons discussed in Section II.B.1 of this Opinion, I find Gillespie’s testimony that he and Eddings were responsible for all aspects of the introducer sheath design in the subassembly drawing not credible.

45. Gillespie also described Plaintiff’s contribution to the final design as “the bulbous shape, sort of hourglass shape[, depicted] in Figures 5 and 7 [of the D’839 Patent] in which the handles take a sort of circular shape in the exterior into the extremities of the handle.” (Id. at 209:20–210:4.)

46. In a previous lawsuit involving Eddings, Galt Medical, Xentek, and the D’839 Patent, Gillespie never claimed that he or Eddings were co-inventors of the ornamental features of Plaintiff’s design patent. (Id. at 216:23–217:13, 248:8–243:9.)

47. Xentek created a final prototype of the new introducer sheath design based on Gillespie’s subassembly drawing and sent it to Plaintiff in January 1999. (Pl.’s Ex. 15; N.T., Vol. 2, 36:3–38:2, 39:5–22.) Plaintiff was “really excited” when he received the final prototype because all of the features of his design were included. (N.T., Vol. 2, 36:5–11, 37:20–24.) Plaintiff thought that in the period after this “sequence of product development,” Xentek was refining the mold and was going to make some prototype samples for Plaintiff to show to a few select people and to also “make sure that [Plaintiff] didn’t want any other changes to it.” (Id. at 41:2–8.) Similar to his agreement with Prepro, Plaintiff thought that, once the design was finalized, Eddings and Galt Medical would manufacture the product embodying his design and sell it to him in “bulk non-sterile.” (Id. at 42:4–18.) Plaintiff would then sell the introducer in his company’s kits. (Id.)¹

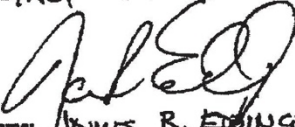
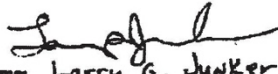
¹ Plaintiff was never employed by Galt Medical or Xentek or any company that Eddings owned. (N.T., Vol. 4, 9:20–22.)

48. In January 1999, Plaintiff and Eddings signed another NDA but this time Eddings signed on behalf of Xentek. (See Pl.'s Ex. 12.) At trial, Defendants disputed that the signature on this NDA was Eddings's. (N.T., Vol. 2, 53:12–15.) Yet, Defendants agreed to the admission of the NDA and chose not to cross examine Plaintiff on the veracity of the signature when given the opportunity. (Id. at 54:16–24.)

49. This NDA, signed by Plaintiff and Eddings on January 4, 1999, was to the benefit of both Plaintiff and his partner at the time, John Thorniley. (N.T., Vol. 2, 51:2–8.) The NDA was faxed on January 8, 1999 to Plaintiff from “Jim.” (Pl.'s Ex. 12 at 1.) Plaintiff understood “Jim” to be Eddings. (N.T., Vol. 2, 54:6–11.) The NDA states: [“Xentek Medical Inc.”] “realizes that Larry G. Junker & John D. Thorniley . . . (hereinafter referred to as ‘DISCLOSER’) is in possession of certain technical information relating to: TRANSITIONLESS SHEATH IMPROVED VALVE FOR INTRODUCER, which is considered confidential and in which DISCLOSER has a proprietary interest.” (Pl.'s Ex. 12 at 2.)

50. The NDA was signed on January 8, 1999 by Eddings, as demonstrated in part by the below signature comparison.

August 13, 1998 NDA signed by Eddings and Plaintiff
(N.T., Vol. 4, 67:12–72:8; Pl.'s Ex. 7.)

<p>On behalf of: GACT MEDICAL CORP</p>  <p>Name: JAMES R. EDDINGS Title: PRESIDENT Date: 8-13-98 Company: GACT MEDICAL CORP Address: 2475 MERITT DR CARLISLE TX 75004</p>	<p>On behalf of: MSI</p>  <p>Name: Larry G. Junker Title: President Date: 8-13-98 Company: MSI Address: 615 Jasmine Ave. N. Tarpon Springs, FL</p>
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January 8, 1998 NDA signed by Eddings and Plaintiff
(Pl.'s Ex. 12.)

5. It is agreed that any dispute shall be resolved in and interpreted under the laws of the State of Florida.

RECIPIENT: Xentek Medical, Inc.

ADDRESS: 636 E. 16th St., Attn: TX 75751

By: [Signature] X Date 1/8/99
Authorized Signature of Officer

By: [Signature] Date 1-4-99
Larry G. Junker & John D. Thorniley
Authorized Signatures

51. Gillespie was unaware of this second NDA signed by Plaintiff and Eddings in January 1999. (Gillespie Tr. Dep., 180:19–181:6.)

52. On January 13, 2000, after working on the introducer sheath product at Xentek, Gillespie applied for a utility patent, “intended to cover the locking mechanism that was used in [Xentek’s] product.” (Gillespie Tr. Dep at 184:25–185:2.) United States Patent Number 6,336,914 (the “Gillespie Patent”) for “Releasable Interlock Assembly Having Axial and Rotational Engagement,” was issued to Gillespie by the PTO on January 8, 2002. (Defs.’ Ex. 104).

53. Plaintiff was informed of the Gillespie Patent by one of his customers. (N.T., Vol. 2, 44:25–45:8.)

54. Thereafter, Plaintiff called his patent attorney and applied for the D’839 Patent on February 7, 2000. (*Id.* at 55:5–7.) The D’839 Patent did not disclose the Gillespie Patent. (*See* Pl.’s Ex. 1.) As part of his patent application, Plaintiff swore that he was the first and sole inventor of the subject matter claimed in the D’839 Patent. (Defs.’ Ex. 17(B).)

55. In December 1999 or January 2000, Plaintiff called Gillespie asking him for a copy of the design drawings for the tearaway introducer. (Gillespie Tr. Dep., 126:4–10.) Plaintiff did

not tell Gillespie why he wanted the drawings or that they were for Plaintiff's patent application. (Id. at 126:21–22, 130:1–3.) Gillespie asked Eddings's permission before sending the drawings to Plaintiff. (Id. at 127:6–12.)

56. The Figures in the D'839 Patent are different from Gillespie's patent. (Id. at 186:8–12.) In addition, the drawings that Gillespie sent to Plaintiff were not the same drawings used in the D'839 Patent. (Id. at 28:1–15.)

57. A draftsman for Plaintiff's patent attorney prepared the drawings in the D'839 Patent. (N.T., Vol. 2, 55:5–56:7; id. at 229:7–17.)

58. The locking mechanism of Gillespie's utility patent was a functional aspect of the product. (Id. at 185:3–10.) The Gillespie Patent was not intended to claim the handle or ornamental features of the product and was, therefore, not intended to be a design patent. (Id. at 186:4–7, 215:25–216:19.)

D. The Texas Litigation and the PTO's Re-Examination of the D'839 Patent

59. The issue of whether Plaintiff invented the design claimed in the D'839 Patent was raised in a previous lawsuit involving Eddings and his companies, Galt Medical and Xentek, and is pertinent to a number of the issues before me.

60. In January 2003, after learning that Galt Medical was selling introducers encompassing his design without permission, Plaintiff brought suit in the United States District Court for the Northern District of Texas, alleging that Eddings, Galt Medical, and Xentek had infringed the D'839 Patent. (N.T., Vol. 2, 65:22–24.)

61. The jury returned a verdict in Plaintiff's favor in that case, finding that Plaintiff was the first inventor of the design claimed in the D'839 Patent and that Eddings, Galt Medical, and Xentek willfully infringed the patent. (Pl.'s Ex. 20 at A21.) Thereafter, the court entered judgment

for Plaintiff, awarding \$813,550 in damages, \$41,118.62 in pre-judgment interest, and \$275,000 in attorneys' fees. (N.T., Vol. 2, 65:25–66:3; N.T., Vol. 4, 51:23–52:10; Pl.'s Ex. 20 at A21); see also Junker v. Eddings, No. 02-0172, 2004 WL 5552032 (N.D. Tex. Jan. 16, 2004).²

62. Eddings, Xentek, and Galt Medical were also enjoined from selling their introducer sheath product and required to provide Plaintiff with the names of their customers who bought the infringing product, which included Defendants in this case, so that Plaintiff could inform those customers of the injunction. (Pl.'s Exs. 21, 22, 22.1; see also N.T., Vol. 6, 4:1–8.)³

63. Galt Medical was also found to have breached the Non-Disclosure Agreement signed by Plaintiff and Eddings in August 1998. (Pl.'s Ex. 20 at A19.)

64. On appeal, the United States Court of Appeals for the Federal Circuit affirmed this judgment, vacating only the award of attorneys' fees and remanding to the district court for further proceedings. See generally Junker v. Eddings, 396 F.3d 1359 (Fed. Cir. 2005).

² Gillespie was not named as a defendant in the Texas lawsuit but was deposed and testified at trial. (Gillespie Tr. Dep., 176:12–18, 216:23–217:13, 242:8–243:9.) In the case before me, remarkably, Gillespie did not initially recall that he testified at the Texas trial, even after being shown a transcript of his trial testimony. (Id. at 179:3–6, 188:15–25.) Eventually, after being shown additional documents at his trial deposition in this matter, Gillespie's recollection was refreshed regarding his testimony in the prior case. (Id. at 216:23–217:13, 242:8–243:9.)

³ Defendants dispute that they ever received a letter that informed them of the injunction against Eddings, Galt Medical, and Xentek for infringement of the D'839 Patent. "Under the mailbox rule, if a letter 'properly directed is proved to have been either put into the post-office or delivered to the postman, it is presumed . . . that it reached its destination at the regular time, and was received by the person to whom it was addressed.'" Lupyan v. Corinthian Colleges, Inc., 761 F.3d 314, 319 (3d Cir. 2014). Here, Plaintiff presented at trial a delivery confirmation receipt from the United States Postal Service, showing that the January 9, 2004 injunction letter was mailed to Lisa Chatburn at MedComp. (Pl.'s Exs. 22, 23 (LJ 04106).) Defendants neither produced Ms. Chatburn as a witness to dispute receipt of the letter nor offered her sworn statement. Thus, I find that Defendants have failed to overcome the presumption that MedComp received the letter informing Defendants of the injunction.

65. Following the conclusion of the Texas litigation, in 2004, the PTO re-examined the D’839 Patent. (Pl.’s Ex. 1; N.T., Vol. 2, 80:22–24.) The Gillespie Patent was disclosed as part of the reexamination as well as additional patents, publications, and other written documents for the PTO’s consideration. (Pl.’s Exs. 1, 75, 76; N.T., Vol. 2, 81:7–83:3.) At the conclusion of the reexamination, the PTO upheld the D’839 Patent’s validity and its single design claim. (Pl.’s Ex. 1; N.T., Vol. 2, 80:25–81:6.)

E. The Accused Products

66. After Defendants were informed that Galt Medical was enjoined from selling them its introducer sheath product, Defendants developed their own. (See N.T., Vol. 6, 4:1–8; Pl.’s Exs. 21, 22, 22.1; Defs.’ Exs. 160, 161.)

67. Defendant Martech manufactured Defendants’ tearaway introducer sheath products: the Super Sheath, the Super Sheath 2.0, the Super Sheath Valved Tearaway, and the Super Sheath Valved Tearaway 2.0 (the “Accused Products”).⁴ (Pl.’s Exs. 17, 18, 19(a), 19(b).) The sheath of the Accused Products was manufactured separately from the handle and also made of a different material. (N.T., Vol. 5, 115:2–116:6; N.T., Vol. 8, 11:6–12:6.) Defendant Martech bought the sheath from a third-party vendor, inserted the sheath into Martech’s mold for the handle, and then melted plastic in the handle mold around that sheath, bonding the handle and sheath together. (*Id.*; see also N.T., Vol 8, 55:23–56:10.) Defendants did not sell the handle separately. (N.T., Vol. 8, 57:24–58:2.)

68. Martech sold the Accused Products individually to Defendant MedComp as well as

⁴ The Super Sheath and Super Sheath 2.0 are the same design, but they are made of different materials. (N.T., Vol. 7, 42:14–43:6.) The two Valved Tearaway products share the same basic design, but there are minor differences in the valve. (N.T., Vol. 8, 25:20–27:23.)

other customers. (N.T., Vol. 8, 9:8–13, 12:9–14.) MedComp, in turn, sold the Accused Products in kits. (Id. at 73:10–74:4; Defs.’ Ex. 163.) These kits, such as MedComp’s nursing kit, contained dozens of items, including a gown, a mask, a tourniquet, a tape measure, a catheter, a needle, a guidewire, and the tearaway introducer sheath. (N.T., Vol. 5, 17:20–18:1, 74:14–75:8; see also Pl.’s Ex. 28.) And the introducer sheath was one of the “top four” items sold in this kit. (N.T., Vol. 6, 8:9–22.)

69. Defendant Martech sold the accused Super Sheath products from February 15, 2010 to December 27, 2013. (N.T., Vol. 9, 31:21–24; Defs.’ Ex. 161.) Defendant MedComp sold the accused Super Sheath products from January 15, 2013 to May 6, 2014. (Id. at 32:1–11; Defs.’ Ex. 161.) Martech sold the accused Valved Tearaway products from July 15, 2009 to March 4, 2014. (Id. at 31:4–9; Defs.’ Ex. 160.) MedComp sold the accused Valved Tearaway products from August 25, 2009 to April 23, 2014. (Id. at 30:22–31:1; Defs.’ Ex. 160.)

70. Sales spreadsheets produced by Defendants show the sales figures for each of the Accused Products, ranging from the date of the first sale to the date of the last sale: Defendants’ Exhibit 156a showed MedComp’s kit sales; Defendants’ Exhibit 157a showed Martech’s individual introducer sheath sales; and Defendants’ Exhibit 158a showed Martech’s kit sales. Defendants’ gross profits, identified in these spreadsheets, was calculated by deducting material, labor, and overhead costs from Defendants’ net sales. (N.T., Vol. 9, 105:15–19.)

71. Defendants also identified, in Defendants’ Exhibits 156a and 158a, each kit in which one of the Accused Products was sold and, in Defendants’ Exhibit 162, the type of Accused Product contained in each kit.

F. Evidence Concerning Infringement

72. On August 8, 2013, Plaintiff filed a complaint alleging patent infringement against Defendants regarding the manufacture and sale of the Accused Products. Plaintiff initiated this action after seeing Defendants' products displayed at a trade show in 2006. (N.T., Vol. 2, 83:20–85:20; Pl.'s Ex. 28.) Defendants had a brochure for each of the Accused Products at this trade show, showing an introducer with “upswept large eared handles.” (*Id.*) Plaintiff requested samples of the products from a salesperson, which were later sent to him. (*Id.*)

73. Peter Bressler testified as Plaintiff's expert on design patent infringement. Bressler is a University of Pennsylvania professor in industrial design and ergonomics with a master's degree in integrated product design. (N.T., Vol. 6, 75:4–80:9; Pl.'s Ex. 38.) Impressively, his experience includes over forty-five years of consulting on design patents. (*Id.*)

74. Bressler's analysis centered on the ordinary observer's overall visual impression of the Accused Products as compared to the overall visual impression of the claimed design, which is depicted by each of the Figures in the D'839 Patent. (N.T., Vol. 6, 84:2–89:2; Pl.'s Ex. 1.) To aid his testimony on this issue, Bressler created the following exhibit, which depicts the Accused Products alongside Figures⁵ from the D'839 Patent:

⁵ Bressler testified at trial that although he reviewed all Figures in the D'839 Patent in forming his opinion, he included only Figures 1, 5, and 7 in the above diagram for “the sake of space” and “because [he] felt that these views were the ones that most clearly communicated what an ordinary observer would see.” (N.T., Vol. 6, 90:25–91:15.)

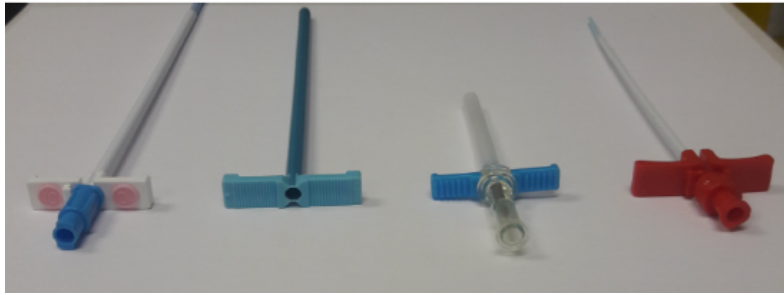
¾ view Fig.1	Top view Fig. 5	Bottom view Fig. 7	
			The D'839 Patent (Pl.'s Ex. 1.)
			Super Sheath (Pl.'s Ex. 17)
			Super Sheath 2.0 (Pl.'s Ex. 19(a))
			Valved Tearaway (Pl.'s Ex. 18)
			Valved Tearaway 2.0 (Pl.'s Ex. 19(b))

(See Pl.'s Ex. 39.)

75. I accept the following opinions offered by Bressler at trial:

- The visual impression evoked by the D'839 Patent's Figures is "a pair of lobular or Mickey Mouse-shaped ears . . . that are attached to a conical part in the center . . . and they have ribs on the top and ribs on the bottom and a specific curvature [away from the hub] and radius on the edges . . ." (N.T., Vol. 6, 89:18–90:6, 108:3–7.)
- Based on these Figures and the Accused Products, the ears or tabs would receive an ordinary observer's "primary level" of attention when viewing the whole product as a unit. (N.T., Vol. 6, 92:24–93:5.) The ribs and the shape of the hub would also receive the ordinary observer's attention, but the ears would predominate as the "primary visual element." (*Id.* at 94:4–7.)
- As shown by Plaintiff's Exhibit 39, the design of each of the Accused Products, as a whole, is substantially similar to the claimed design.
- The substantial similarity between the Accused Products and the claimed design is

“accentuated by the fact that the prior art ahead of the patent had nothing like [the] kind of ears [depicted in the D’839 Patent and included in the Accused Products].” (N.T., Vol. 6, at 93:21–94:6, 107:7–14, 23–108:2.) As shown below (Pl.’s Exs. 3, 24,⁶ 41), the element that primarily contributes to the overall visual impression of the claimed design, the upswept, “Mickey Mouse” ear-shaped tabs, significantly departed from the flat, mostly rectangular handles depicted in the prior art. (See id.; see also Defs.’ Exs. 8, 9, 11.) The Accused Products have each copied this ear shape, creating substantially the same overall visual impression as the claimed design. (Pl.’s Exs. 17, 18, 19(a), 19(b).)



⁶ The handles in Plaintiff’s Exhibit 24 labelled MAR00001, MAR00003, MAR00007, and MAR00009 are the Accused Products. (See Defs.’ Exs. 133, 124, 128, 130.)

76. Bressler concluded that the Accused Products were substantially similar to the claimed design, but he recognized minor differences. For instance, in comparing the Figures of the D’839 Patent to Defendants’ Super Sheath products, Bressler agreed that the curvature of the ears was different but did not find that curvature to be “very differentiated” from the claimed design: “[Y]ou’re looking at percentages of millimeters in terms of change of radius.” (N.T., Vol. 6, 96:19–97:1.) I accept this opinion.

77. As another example, regarding the first-generation Valved Tearaway product, Bressler noted that (1) this accused product was “close” to being substantially the same, (2) was “a little less likely than some of the other designs” to confuse the ordinary observer as compared to the claimed design, and (3) the “stepped” hub of the Valved Tearaway was “one of the features that [gave Bressler] a little hesitation about saying it’s substantially the same.” (N.T., Vol. 6, 97:21–22, 103:7–11, 105:22–106:5.) Ultimately, Bressler concluded that the Valved Tearaway product was “basically the same in terms of its visual concept” and “an ordinary observer would potentially confuse it for what was in the patent.” (*Id.* at 97:17–19.) I accept this opinion.

78. The minor differences between the Accused Products and the claimed design, such as those recognized by Bressler, were the primary focus of the testimony of Defendants’ design expert, Richard Meyst.⁷

79. Meyst has never consulted on a design patent. Meyst testified that the claimed design depicts ribs on both the top and bottom of each handle tab. He distinguished the ribs on the Super Sheath products by pointing out that the D’839 Patent contains “different numbers of ribs on the proximal and distal surfaces of the wings.” (N.T., Vol. 7, 46:19–47:8.) Meyst also posited

⁷ (N.T., Vol. 7, 30:7–24, 32:13–15, 33:10–17, 34:18–21, 35:9–13, 36:17–37:4, 39:3–23, 43:9–22, 44:2–3, 45:17–46:2, 46:19–47:8, 48:1–6.)

that an ordinary observer would be able to distinguish the claimed design from the Accused Products because (1) Figure 6 in the claimed design displays a “large radius on the distal side of the end and then a very sharp corner or small radius” at the edge, and the Super Sheath has rounded edges, (2) when viewed from the angle of the user, the Valved Tearaway products’ handles appear “elliptical in nature,” or (3) instead of depicting a notch configured as a “V” section on either side of the hub, the Valved Tearaway products include the notch as “a rectangular section with a very small, pointed V section deep into the part.” (Id. at 45:17–46:2.; see also id. at 33:10–17, 34:18–21, 36:24–37:4.)

80. Meyst acknowledged that “the enlarged rounded ears” of the claimed design are the “biggest difference” or departure from the prior art.⁸ (N.T., Vol. 7, 88:1–8.) Meyst also testified that the Figures in the Gillespie Patent were similar to Figure 7 in the D’839 Patent and that the Figures in the Gillespie Patent were similar in design to the Accused Products:

Q: Do you remember in math when A equals B and B equals C and A equals C? Do you remember this?

A: I do.

Q: Okay. So here you’re saying that this drawing [from the Gillespie Patent] is similar to the design to the [D’839 Patent] drawing, Figure 7 in this case. And you just said the accused devices have a similar circularity as this drawing shown here - - that you say [is] similar is design, is that right?

A: Yes.

(Id. at 102:16–21.)

81. Having carefully considered, as the factfinder, Meyst’s opinions, I will accept Bressler’s conclusion that the ordinary observer would not focus on differences like those

⁸ Gillespie also acknowledged the claimed design’s departure from the prior art. (Gillespie Tr. Dep., 271:15–22.)

identified by Meyst when making a purchasing decision. I agree with Bressler that to the ordinary observer, who is usually a “nurse or the supporting staff” at a hospital, the minor differences between the Accused Products and the claimed design would “just not [be] important enough.” (N.T., Vol. 6, 94:17–95:11.) As Bressler stated, “[a] purchasing agent gathers a bunch of people around to give quotes on things at a sales point, and it goes through the system with nobody ever really looking at it very much to see what it is.” (Id.)

82. Meyst acknowledged that the “design and shape” of the introducer sheath were not important to those individuals making the purchasing decisions for these products. (N.T., Vol. 7, 103:8–16.)

83. Michael Anstett, a former employee of Defendant MedComp and registered nurse, also testified that the handle of the introducer sheath was of no consequence to the insertion itself and not one of the factors valued by an ordinary observer when buying a dilator. (N.T., Vol. 5, 18:2–20:5.)

84. According to Defendants’ President, Timothy Schweikert, and Defendant Martech’s Vice President of Engineering, Kevin Sanford, the handle on each of the Accused Products was similar to the claimed design. (N.T., Vol. 6, 39:18–20; N.T., Vol. 8, 58:3–60:2; Schweikert Dep., Defs.’ Ex. 121, 186:19–22.) This similarity was why Schweikert changed the handle design of the Accused Products after Defendants were made aware of this lawsuit. (N.T., Vol. 8, 58:3–60:2; Schweikert Dep., Defs.’ Ex. 121, 173:7–16.) Schweikert thought the Accused Products “looked too much like” the claimed design. (N.T., Vol. 8, 58:3–60:2.)⁹

⁹ Defendants object in their post-trial briefing to admission of “[a]ny testimony to the effect that the design was changed so that it did not resemble the design claimed in the D’839 Patent” because this testimony is reflective of a subsequent remedial measure under Federal Rule of Evidence 407. This rule states: “When measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove . . .

85. In fact, according to Schweikert, the only feature of the Accused Products that Defendants redesigned was the “Mickey Mouse” ear-shape of the tabs: “[w]hat we did is, instead of having the round shape, we just squared it off into more of a rectangular shape. . . . [W]e kept smooth edges . . . on the grips . . . of the hub here, and that was pretty much . . . the difference between . . . if you’re asking me about the hub section. So the difference is that we eliminated . . . the round shape . . . which people are referring to as ‘Mickey Mouse’ . . . and went straight.” (N.T., Vol. 5, 82:16–24.)

II. LEGAL ANALYSIS

A. Patent Infringement

1. Applicable Precedent

Design patent infringement occurs when someone “during the term of a patent for a design, without license of the owner,”

(1) applies the patented design, or any colorable imitation thereof, to any article of manufacture for the purpose of sale, or (2) sells or exposes for sale any article of manufacture to which such design or colorable imitation has been applied

35 U.S.C. §289 (2018). A patentee must prove design patent infringement by a preponderance of the evidence. Braun Inc. v. Dynamics Corp. of Am., 975 F.2d 815, 819 (Fed. Cir. 1992).

“Determining whether a design patent has been infringed is a two-part test: (1) the court first construes the claim to determine its meaning and scope; (2) the fact finder then compares the properly construed claim to the accused design.” Lanard Toys Ltd. v. Dolgencorp LLC, 958 F.3d 1337, 1341 (Fed. Cir. May 14, 2020). When comparing the claimed design to the accused design,

culpable conduct.” Fed. R. Evid. 407. I will overrule this objection for several reasons. First, Defendants did not object to this testimony at trial or the admission of deposition testimony about the same subject matter. Second, my Finding of Facts rely upon the statements by Defendants’ own President and Vice President of Engineering that the Accused Products and the claimed design were similar. Thus, I am not relying on remedial measures.

the court applies the “ordinary observer test.” Egyptian Goddess, Inc. v. Swisa, Inc., 543 F.3d 665, 678 (Fed. Cir. 2008). Under this test, a design patent is infringed “if, in the eye of an ordinary observer, giving such attention as a purchaser usually gives, two designs are substantially the same, if the resemblance is such as to deceive such an observer, inducing him to purchase one supposing it to be the other.” Ethicon Endo-Surgery, Inc. v. Covidien, Inc., 796 F.3d 1312, 1335 (Fed. Cir. 2015) (quoting Egyptian Goddess, 543 F.3d at 671).

The ordinary observer is a hypothetical person “of ordinary acuteness” who examines the article with the same “degree of observation which men of ordinary intelligence give.” Gorham Co. v. White, 81 U.S. 511, 528 (1871)); see also Egyptian Goddess, 543 F.3d at 672. While the ordinary observer is not an expert, they are familiar with the prior art and are “either a purchaser of, or sufficiently interested in, the item that displays the patented designs” Arminiak & Assocs., Inc. v. Saint-Gobain Calmar, Inc., 501 F.3d 1314, 1323 (Fed. Cir. 2007), overruled on other grounds by Egyptian Goddess, 543 F.3d at 678; see also Goodyear Tire & Rubber Co. v. Hercules Tire & Rubber Co., Inc., 162 F.3d 1113, 1117 (Fed. Cir. 1998), overruled on other grounds by Egyptian Goddess, 543 F.3d at 678.

When proving substantial similarity, the differences between the patented design and accused design “must be evaluated in the context of the claimed design as a whole, and not in the context of separate elements in isolation.” Ethicon Endo-Surgery, 796 F.3d at 1335. A court should not conduct an element-by-element comparison of the designs’ ornamental features. See id.

Also, a design patent is “not limited to a particular size, color or construction material, ‘such factors should not be taken into consideration in performing an infringement analysis.’” See Lanard Toys Ltd. V. Toys “R” Us-Delaware, Inc., No. 15-849, 2019 WL 1304290, at *10 (M.D.

Fla. Mar. 21, 2019), aff'd by 958 F.3d 1337 (Fed. Cir. 2020) (quoting Hutzler Mfg. Co., Inc. v. Bradshaw Int'l., Inc., No. 11-7211, 2012 WL 3031150, at *12 (S.D.N.Y. July 25, 2012) (collecting cases)); see also Unique Functional Prods., Inc. v. Mastercraft Boat Co., Inc., 82 F. App'x 683, 690 (Fed. Cir. 2003).

An infringement analysis must also include “a comparison of the asserted design against the prior art: ‘if the accused design has copied a particular feature of the claimed design that departs conspicuously from the prior art, the accused design is naturally more likely to be regarded as deceptively similar to the claimed design, and thus infringing.’” Apple Inc. v. Samsung Elecs. Co., Ltd., 786 F.3d 983, 999 (Fed. Cir. 2015), reversed on other grounds by, 137 S. Ct. 429 (2016) (quoting Egyptian Goddess, 543 F.3d at 678). In other words, “[i]n some instances, the claimed design and the accused design will be sufficiently distinct that it will be clear without more that the patentee has not met its burden of proving the two designs would appear substantially the same to the ordinary observer” Egyptian Goddess, 543 F.3d at 678. “When the claimed and accused designs are not plainly dissimilar, resolution of the question whether the ordinary observer would consider the two designs to be substantially the same will benefit from a comparison of the claimed and accused designs with the prior art” Id. Such comparisons, however, must still be used to determine “whether the accused design has appropriated the claimed design as a whole.” Id. at 677. Purchaser deception occurs as “a result of the similarities in the overall design, not of similarities in ornamental features in isolation.” Amini, 439 F.3d at 1371. Finally, “minor differences between a patented design and an accused article’s design cannot, and shall not, prevent a finding of infringement.” Crocs, Inc. v. Int’l Trade Comm’n, 598 F.3d 1294, 1303 (Fed. Cir. 2010) (quoting Payless Shoesource, Inc. v. Reebok Int’l Ltd., 998 F.2d 985, 991 (Fed. Cir. 1993)).

2. Analysis

The D’839 Patent contains a single claim, “[t]he ornamental design for a handle for introducer sheath, as shown and described,” (Pl.’s Ex. 1.), which I construed as follows: “The D’839 Patent claims the ornamental design of a handle for an introducer sheath, as shown in Figures 1–9. The broken lines in the Figures of the D’839 Patent represent unclaimed subject matter.” (ECF No. 192.) The introducer sheath handle, shown in solid lines, has two bulbous, “Mickey Mouse” ear-shaped tabs on the handle, which are connected in the center by a cone-shaped “hub,” into which the sheath is inserted. “Ribs” are also depicted on the top and bottom of each handle tab.

Plaintiff argues that the primary ornamental feature of this design is the “enlarged rounded ears,” which are present in all of the Accused Products. According to Plaintiff, the Accused Products and the claimed design all have an upswept wing configuration, with a similar configuration of “ribs” on the top and bottom surfaces of the wings.

Plaintiff points out that Timothy Schweikert (President of both Defendants) and Kevin Sanford (Vice President of Engineering at Martech) admitted that “ordinary observers given the amount of time they would give to a purchase of this type would think the accused designs are similar,” and, in fact, redesigned the Accused Products for that reason. (Pl.’s Br. at 9.)

Plaintiff also emphasizes that a design patent is not limited by a particular size, color, or material, so any distinction that Defendants made at trial regarding the size of the hub or the “French” sizes available for each product is irrelevant.

Finally, Plaintiff asserts that when comparing the claimed design and the Accused Products to the prior art, it is clear that the enlarged, rounded, upswept ears of the D’839 Patent stand out as

a “total departure” from the prior art and that the Accused Products are much closer to the claimed design than the prior art. (Pl.’s Br. at 11.)

Defendants respond that “the ordinary observer would not be induced to purchase the accused products by the design of the handle” but would likely notice “differences in designs . . . no matter how small.” (*Id.* at ¶¶ 89, 90.) Defendants highlight the following differences between the Accused Products and the claimed design:

The D’839 Patent claims a conical tapered cone that blends with a fillet into the tabs on the sides of the handles. By contrast, the Super Sheath products utilize “two cylinders of different diameters stacked upon each other” rather than a tapered cone. . . . Both experts testified that the hub makes up about 40% of the overall visual impression of the D’839 Patent. . . .

Figure 6 of the D’839 Patent illustrates a swept-back, curved wing not present in the Super Sheath products. The wings in Figure 6 also display a “large radius on the distal side of the end and then a very sharp corner or small radius” at the edge. The Super Sheath, however, has rounded edges.

The D’839 Patent and the Super Sheath both contain ribs on the wings; however, [t]he D’839 Patent contains different numbers of ribs on the proximal and distal surfaces of the wings than the Super Sheath products. The Super Sheath contains a raised rectangular section in the center of the handle that contains its own ribs. The D’839 Patent lacks this feature. . . .

The Valved Tearaway V1 and V2 do not have the curvature shown in the handles in Figure 6 of the D’839 Patent. Instead, as Meyst explained, the Valved Tearaway products have “three sections. The middle section is perpendicular to the longitudinal access, and has a flat surface, and on either side, articulating off at about a 45-degree angle, are the two handles. So, there is no curvature. It’s made up of three flat elements.” . . .

Where the D’839 Patent shows round, “Mickey Mouse” shaped tabs at the ends of the handles, the Valved Tearaway V1’s tabs appear as elliptical in nature when viewed from the angle of the user of the product. . . .

The Valved Tearaway V2 has angular handles that “attach into the conical section, about midway up,” whereas, the D’839 Patent claims handles that attach at the base of the hub. . . .

In the D’839 Patent, “the notch is configured as a V section on either side of the hub.” In the Valved Tearaway products, “the notch . . . is a rectangular section

and it has a very small, pointed V section deep into the part to facilitate tearing.” .
..

The Valved Tearaway products contain an obvious external locking feature that is absent in the design claimed by the D’839 Patent. . . .

The Valved Tearaway hub, specifically the Valved Tearaway V2, is significantly larger and more robust than the hub of the D’839 Patent. This difference is significant, as both experts agreed that the hub creates at least 40% of the overall visual impression of the D’839 Patent.

(Id. at ¶¶ 58–60, 62–67 (citations omitted).)

For the following reasons, I conclude that Plaintiff has proven by a preponderance of the evidence that the design of each of the Accused Products, as a whole, is substantially similar to that of the claimed design.

First, Plaintiff’s design expert Peter Bressler’s testimony was both credible and persuasive regarding the Accused Products’ substantial similarity to the claimed design in the eyes of an ordinary observer. To aid in his testimony regarding this comparison, Bressler presented an exhibit, depicted in Paragraph 76 of my Findings of Fact, showing Figures in the D’839 Patent and the Accused Products side-by-side. (Pl.’s Ex. 39.) This exhibit is particularly persuasive in demonstrating the substantial similarities between the Accused Products and claimed design. As Bressler concluded and as evidenced by this exhibit, the ears or tabs of the Accused Products would receive an ordinary observer’s primary level of attention when viewing the whole product as a unit. (N.T., Vol. 6, 92:24–93:5.) And, although Bressler identified the ribs and the shape of the hub as elements also receiving attention from the ordinary observer, I conclude that the ears predominate as the primary visual element.

Second, the substantial similarity between the Accused Products and the claimed design is also highlighted by the design’s visual departure from the prior art. (N.T., Vol. 6, at 93:21–94:2.) The predominating visual element of the claimed design’s overall visual impression, the upswept,

“Mickey Mouse” ear-shaped tabs, differ significantly from the flat, mostly rectangular handles depicted in the prior art. (Pl.’s Exs. 3, 24, 41; Defs.’ Exs. 8, 9, 11; Id. at 94:3–6.) The Accused Products have each copied this ear shape, creating the same overall visual impression as the claimed design. (N.T., Vol. 6, 107:7–14, 23–108:2.) This further supports my finding that an ordinary observer would be deceived into thinking that the Accused Products were the claimed design. See Apple Inc., 786 F.3d at 999. Even Defendants’ own design expert, Meyst (who I find to be less qualified and less credible than Bressler) acknowledged this visual departure from the prior art. (N.T., Vol. 7, 88:1–8; Gillespie Tr. Dep., 271:15–22 (Gillespie acknowledging the same).)

Third, Meyst and Defendants’ President, Schweikert, admitted that the handle of the Accused Products and the Figures in the D’839 Patent were similar. (See N.T., Vol. 7, 102:16–21; N.T., Vol. 6, 39:18–20; Schweikert Dep., Defs.’ Ex. 121, 186:19–22.) In fact, this similarity is why Schweikert changed the handle design of the Accused Products after Defendants were made aware of this lawsuit. (N.T., Vol. 8, 58:3–60:2; Schweikert Dep., Defs.’ Ex. 121, 173:7–16.) And the only feature of the Accused Products that Defendants redesigned was the “Mickey Mouse” ear shape of the tabs. (N.T., Vol. 5, 82:16–24.)

In reaching these conclusions, I have carefully considered that the Accused Products, particularly the Valved Tearaway, are not identical to the D’839 Patent’s design. (N.T., Vol. 6, 96:19–97:1, 97:21–22, 103:7–11, 105:22–106:5.)¹⁰ But despite the differences, it remains that the Accused Products are substantially the same as the claimed design based on an overall visual

¹⁰ The handles of the Valved Tearaway products are (1) upswept at a sharper angle than the claimed design, (2) the hub of the first-generation Valved Tearaway is stepped, instead of a smooth, conical shape, and (3) although design patents are not limited by a particular size, the hub of the Valved Tearaway products are larger in proportion to the tabs.

impression dominated by the shape of the tabs. Crocs, Inc., 598 F.3d at 1303 (Fed. Cir. 2010) (“[M]inor differences between a patented design and an accused article’s design cannot, and shall not, prevent a finding of infringement.”).

Defendants’ element-by-element comparison of the claimed design and the Accused Products has been expressly rejected by the Federal Circuit. See Ethicon Endo-Surgery, 796 F.3d at 1335. Rather than focus on the overall visual impression of the designs, Defendants compare the minute differences in each element of the Accused Products in isolation, which, they assert, add up to plainly dissimilar or sufficiently distinct designs.¹¹

For instance, the claimed design depicts ribs on both the top and bottom of each handle tab. Defendants attempt to distinguish the ribs on the Super Sheath products by pointing out that the D’839 Patent contains “different numbers of ribs on the proximal and distal surfaces of the wings.” (N.T., Vol. 7, 46:19–47:8.) Although I am required to compare each design as a whole, Defendants urge me, instead, to count the number of ribs on each tab and, based on the difference in number, conclude that an ordinary observer would be able to distinguish the Super Sheath products from the claimed design.

Defendants also suggest that an ordinary observer would be able to distinguish the claimed design from the Accused Products because (1) Figure 6 in the claimed design displays a “large radius on the distal side of the end and then a very sharp corner or small radius” at the edge, and the Super Sheath has rounded edges, (2) when viewed from the angle of the user, the Valved

¹¹ Plaintiff also argues that Defendants distinguish the functional aspects of the Accused Products from the claimed design. Because the scope of the D’839 Patent is limited to the ornamental features of the claimed design for purposes of infringement, Plaintiff asserts that these functional differences between the Accused Products and the claimed design are not part of their overall visual impression. I agree. See Ethicon Endo-Surgery, 796 F.3d at 1333; (see also N.T., Vol. 5, 89:5–93:9.)

Tearaway products' handles appear "elliptical in nature," and (3) instead of depicting a notch configured as a "V" section on either side of the hub, the Valved Tearaway products include the notch as "a rectangular section with a very small, pointed V section deep into the part." (*Id.* at 45:17–46:2; see also *id.* at 33:10–17, 34:18–21, 36:24–37:4.)

This argument is belied by Defendants' own evidence. To the ordinary observer, likely a nurse or the supporting staff at a hospital, these minor differences would not be important. (N.T., Vol. 6, 94:17–95:11.) Defendants' own witnesses, Meyst and Anstett, acknowledged that the design and shape of the introducer sheath handle would not be important to the ordinary observer. (N.T., Vol. 7, 103:8–16; see also N.T., Vol. 5, 18:2–20:5.) Thus, I conclude that the ordinary observer would not scrutinize these differences to the extent Defendants propose.

For the reasons set forth above, I conclude that all four of the Accused Products infringe the D'839 Patent.¹²

B. Invalidity

Like utility patents, design patents carry a presumption of validity. Ethicon Endo-Surgery, Inc. v. Covidien, Inc., 796 F.3d 1312, 1328 (Fed. Cir. 2015). Therefore, alleged infringers must prove any invalidity defense by clear and convincing evidence. *Id.* Defendants have asserted the

¹² Plaintiff also argues that Defendants willfully infringed the D'839 Patent. A verdict of willful infringement requires a finding "by clear and convincing evidence in view of the totality of the circumstances that [the defendant] acted in disregard of the . . . patent and lacked a reasonable basis for believing it had a right to do what it did." nCube Corp. v. Seachange Int'l, Inc., 436 F.3d 1317, 1318 (Fed. Cir. 2006) (internal quotation marks omitted). As stated above, Defendants received a letter that informed them of an injunction against Eddings, Galt Medical, and Xentek. In that letter, Defendants were informed that the tearaway introducer sheath product, which they bought from Galt Medical, was found to have infringed the D'839 Patent. Because Defendants received this letter notifying them of the D'839 Patent and because Defendants, for the reasons discussed above, subsequently designed their own introducer sheath products with the same rounded-ear design as the D'839 Patent, I find Defendants' infringement to be willful. Plaintiff acknowledges that a finding of willful infringement does not entitle him to enhanced damages. (N.T., Closing Argument, 11/18/2020, at 38:21–39:19.)

following theories regarding the invalidity of the D’839 Patent: incorrect or incomplete inventorship, inequitable conduct, anticipation, obviousness, and a primarily functional design. I address each defense in turn below.

1. Inventorship

i. Applicable Precedent

“A patent is invalid if more or less than the true inventors are named.” Trovan, Ltd.v. Sokymat SA, Irori, 299 F.3d 1292, 1301 (Fed. Cir. 2002). For patents filed before the implementation of the America Invents Act (“AIA”)—March 16, 2013—35 U.S.C. § 102(f) dictated that “[a] person shall be entitled to a patent unless . . . he did not himself invent the subject matter sought to be patented.” 35 U.S.C. § 102(f). Section 102(f) “ma[de] the naming of the correct inventor or inventors a condition of patentability; failure to name them renders a [pre-AIA] patent invalid.” Pannu v. Iolab Corp., 155 F.3d 1344, 1349–50 (Fed. Cir. 1998); In re VerHoef, 888 F.3d 1362, 1367–68 (Fed. Cir. 2018). Because patents are presumed valid, a court must also presume that all named inventors are the true and only inventors. Trovan, 299 F.3d at 1301. A party challenging inventorship therefore needs to prove misjoinder or nonjoinder of inventors by clear and convincing evidence. Id.

“Determining inventorship is nothing more than determining who conceived the subject matter at issue.” In re VerHoef, 888 F.3d at 1365 (internal quotation marks omitted) (citing Sewall Walters, 21 F.3d 411, 415 (Fed. Cir. 1994)). A person conceives an invention when that person forms a “definite and permanent idea of an operative invention, including every feature of the subject matter sought to be patented.” Id. at 1366 (quoting Sewall, 21 F.3d at 415). For an idea to be “definite and permanent,” the inventor must have a “specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan.” Id. (quoting Burroughs

Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1228 (Fed. Cir. 1994)). “An idea is sufficiently ‘definite and permanent’ when ‘only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.’” Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1460 (Fed. Cir. 1998) (quoting Burroughs Wellcome, 40 F.3d at 1228).

An invention can be conceived by more than one inventor. Id. Such joint inventors need not make equal contributions to the invention or contribute to every claim of the patent. Id. To be a joint inventor, one must:

(1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art.

Pannu, 155 F.3d at 1351.

After conception, however, an inventor may “use the services, ideas, and aid of others in the process of perfecting his invention without losing his right to a patent.” Hoop v. Hoop, 279 F.3d 1004, 1007 (Fed. Cir. 2002) (quoting Ethicon, Inc., 135 F.3d at 1460). A person does not become a joint inventor by “merely assisting the actual inventor after conception of the claimed invention.” Ethicon, Inc., 135 F.3d at 1460; see also Hoop, 279 F.3d at 1008 (finding that “merely refin[ing] and perfect[ing]” an invention did not make one a joint inventor). Further, one does not become a joint inventor by “simply provid[ing] the inventor with well-known principles or explain[ing] the state of the art without ever having ‘a firm and definite idea’ of the claimed combination as a whole” Id. Even a person who performs a reduction to practice disclosed in the patent’s specification is not necessarily a joint inventor. Id.

As mentioned, “[t]o show co-inventorship, . . . the alleged co-inventor or co-inventors must prove their contribution to the conception of the claims by clear and convincing evidence.” Ethicon

v. U.S. Surgical Corp., 135 F.3d 1456, 1461 (Fed. Cir. 1998). “However, ‘an inventor’s testimony respecting the facts surrounding a claim of derivation or priority of invention cannot, standing alone, rise to the level of clear and convincing proof.’” Id. (quoting Price v. Symsek, 988 F.2d 1187, 1194 (Fed. Cir. 1993)). “The rule is the same for an alleged co-inventor’s testimony.” Ethicon, 135 F.3d at 1461. “To satisfy the [clear and convincing evidence] burden, the alleged co-inventor must prove his contribution to the conception of the invention by more than his own testimony concerning the relevant facts.” ScentSational Techs. LLC v. PepsiCo, Inc., 773 F. App’x 607, 611 (Fed. Cir. May 16, 2019); Cardiaq Valve Techs., Inc. v. Neovasc Inc., 708 F. App’x 654, 658 (Fed. Cir. Sept. 1, 2017); Ruling Meng v. Chu, 643 F. App’x 990, 994 (Fed. Cir. Apr. 5, 2016); Weaver v. Houchin, 467 F. App’x 878, 880 (Fed. Cir. Mar. 7, 2012).

“Whether the inventor’s testimony has been sufficiently corroborated is evaluated under a ‘rule of reason’ analysis,” which requires “an evaluation of all pertinent evidence . . . so that a sound determination of the credibility of the alleged inventor’s story may be reached.” Id. (internal quotation marks omitted) (citations omitted); Symantec Corp. v. Computer Assocs. Int’l, 522 F.3d 1279, 1295 (Fed. Cir. 2008) (en banc)

“Corroborating evidence may take many forms”:

Often contemporaneous documents prepared by a putative inventor serve to corroborate an inventor’s testimony. Circumstantial evidence about the inventive process may also corroborate. Additionally, oral testimony of someone other than the alleged inventor may corroborate.

Ethicon, 135 F.3d at 1461. However, “reliable corroborating evidence ‘preferably comes in the form of records made contemporaneously with the inventive process.’” ScentSational Techs. LLC, 773 F. App’x at 611 (quoting Gemstar-TV Guide Int’l, Inc. v. Int’l Trade Comm’n, 383 F.3d 1352, 1382 (Fed Cir. 2004)).

Under this analysis, the court considers all pertinent corroborating evidence to determine whether the witness is credible. Lazare Kaplan Int'l, Inc. v. Photoscribe Techs., Inc., 628 F.3d 1359, 1374 (Fed. Cir. 2010). When conducting this analysis, the court considers eight factors:

- (1) the relationship between the corroborating witness and the alleged prior user,
- (2) the time period between the event and trial,
- (3) the interest of the corroborating witness in the subject matter in suit,
- (4) contradiction or impeachment of the witness' testimony,
- (5) the extent and details of the corroborating testimony,
- (6) the witness' familiarity with the subject matter of the patented invention and the prior use,
- (7) probability that a prior use could occur considering the state of the art at the time,
- (8) impact of the invention on the industry, and the commercial value of its practice.

Id.

ii. Analysis

Defendants argue that Plaintiff is not the first and sole inventor of the D'839 Patent because Gillespie and Eddings are the true inventors. Defendants contend that they have presented the following clear and convincing evidence to prove that the design was “invented, at least in part, if not in total, by Eddings and Gillespie”:

- “Junker’s contribution, if any, to the design was the general idea for ‘larger (wider) handles.’ Def. Exh. 17M. His crude sketch and vague suggestion, unaccompanied by any details, does not make him a co-inventor of either the Gillespie Patent or the D’839 Patent, which was derived from the Gillespie Patent, let alone the first and sole inventor. Moreover, by Junker’s own admission, the idea to make the handles larger and wider was given to him by physicians. Thus, his suggestion of such to Eddings was not his own conception.”
- “The evidence supports that Gillespie invented the size and shape of the ribs of the handle and determined the number of ribs and where to include them. Gillespie also invented the backswept wings and determined the curvature, thickness, and design of the wings. The rearward extension, the stress raiser grooves and the frustoconical nose were all invented by Gillespie. Eddings contributed to the contouring and blending of the shape of the handle design.”

- “Though Junker maintained that the ‘Mickey-Mouse’ shaped ears were solely his idea, he presented no evidence about the conception or reduction to practice of the other elements of the handle, included in the claim as depicted in solid lines in the D’839 Patent. *See* Document No. 192 (Claim Construction Order).”
- “The evidence established that Junker intentionally failed to disclose Eddings and Gillespie as at-least co-inventors on his patent application, knowing that certain figures in the D’839 Patent application were essentially identical to Xentek’s design drawings that he obtained from Gillespie without disclosing his intent to use them to apply for his own patent. This renders the D’839 Patent invalid.”

(Defs.’ Br. ¶¶ 100–103, 105.)

Plaintiff responds that between 1996 and 1997, he conceived “a new introducer handle design improving on prior art designs involving a Mickey Mouse eared handle, with an upswept configuration, having ribs on the top and bottom of the handle.” (Pl.’s Br. 16.) Plaintiff explains that:

[He] disclosed all the details of this design to Eddings during a meeting in August 1998, only after execution of a nondisclosure agreement. Then in November 1998, Junker met with Galt and Xentek employees in Dallas, further disclosing his invention to attendees Eddings, Caitlin and Gillespie. Less than a month later, in December 1998, Xentek sought additional information from Junker in order to move forward with the project. Xentek, based on Mr. Junker’s input, then generated preliminary drawings and a rough SLA three-dimensional model sent to Junker for his approval. . . .

The model did not include the final Mickey Mouse ears but had many of the other features Junker disclosed. Plaintiff sent a fax to Eddings advising that he “would really like to see larger (wider) handles,” because “[t]he prospective customers seemed to like this design.” Pl.’s Ex. 11. Gillespie then integrated the rounded ear Mickey Mouse handles into subsequent drawings and a second model, which Gillespie prepared and shared with Plaintiff for his approval. Mr. Junker testified that he was “excited”, and “elated” when Xentek sent him the model that incorporated his envisioned Mickey Mouse shaped handles, thereby reducing his invention to practice.

(Pl.’s Br. 16–17.)

Defendants' primary focus on attacking Plaintiff's evidence of conception is misplaced. The D'839 Patent is presumed valid and thus so is Plaintiff's inventorship. Plaintiff need not offer any proof of conception. Instead, Defendants must overcome the presumption that Plaintiff is the first and sole inventor. In other words, Defendants must demonstrate by clear and convincing evidence that Gillespie and Eddings conceived, at least in part, the claimed design. In their attempt to meet this burden, Defendants rely heavily on the testimony of Gillespie and Eddings. Standing alone, this testimony cannot rise to the level of clear and convincing proof. See Ethicon, 135 F.3d at 1461. Defendants must present evidence to corroborate it, preferably through records prepared contemporaneously with the inventive process. But the documentary evidence of record on which Defendants relies, in fact, undermines a majority of Gillespie and Eddings's testimony.

These documents include: (1) sketches of an introducer sheath prepared by Gillespie and dated November 9, 1998 (Defs.' Exs. 17(G), 17(H)); (2) a memorandum written by Gillespie about the meeting on November 12, 1998 between Eddings, Gillespie, and Plaintiff (Defs.' Ex. 17(E)); (3) a prototype three-dimensional model of an introducer sheath based on Gillespie's November 9, 1998 drawings (Pl.'s Ex. 9); (4) drawings of an introducer sheath prepared by Gillespie and dated August 6, 1999 (Defs.' Ex. 17(N)); and (5) the United States Patent Number 6,336,914 (the "Gillespie Patent" or the "914 Patent") for "Releasable Interlock Assembly Having Axial and Rotational Engagement," issued to Gillespie and applied for on January 13, 2000 (Defs.' Ex. 104).

A careful examination of each of these documents, in conjunction with the testimony of Eddings and Gillespie, leads me to conclude that Defendants have failed to prove, by clear and

convincing evidence, that Eddings and Gillespie invented, in whole or in part,¹³ the claimed design.

Gillespie's Sketches of an Introducer Sheath Dated November 9, 1998

Defendants claim that Gillespie drew sketches of an introducer sheath design on November 9, 1998, a few days before Plaintiff, Eddings, and Gillespie met. According to Defendants, these sketches establish Gillespie's prior conception. I disagree for several reasons.

First, it is disputed that these sketches were created on November 9, 1998. (Pl.'s Dep., Defs.' Ex. 17, 74:14–75:7.) Eddings never informed Plaintiff that he had been working on the design of the introducer sheath handle or had even thought about it before they met on November 12, 1998. And neither Eddings nor Gillespie ever mentioned these early sketches at the meeting a few days later. (N.T., Vol. 2, 39:24–40:9.) Plaintiff points out that because one of these sketches references a competitor's sheath hub product that Eddings asked Plaintiff to bring to the meeting on November 12, 1998, the sketches were backdated. (Pl.'s Dep., Defs.' Ex. 17, 75:1–7.) Plaintiff reasonably questions why Eddings, who “didn't have any manufacturing facilities to make anything like [the introducer sheath] prior to [Plaintiff] coming out there to their facility,” would “sign a confidentiality and nondisclosure agreement before [in August 1998] if he had something like [what is depicted in the November 9, 1998 sketches] in the works.” (Id.)

The questions raised by Plaintiff about the origin of these sketches are persuasive, but whether they were created on November 9, 1998 or another date is inconsequential. None of the

¹³ Defendants alternatively argue that, even though Plaintiff may have invented the “Mickey Mouse” ear-shaped tabs, which I find to be the primary visual element of the overall visual impression of the claimed design, Eddings and Gillespie invented other aspects of the design. I disagree not only for the reasons discussed below, but also because this theory is belied by Defendants' argument and the testimony of their witnesses that those other aspects are either functional or anticipated by the prior art and, therefore, cannot be claimed by the D'839 Patent. (Defs.' Br. ¶¶ 6, 7; Gillespie Tr. Dep., 220:1–223:19; N.T., Vol. 7, 80:12–82:24; Schweikert Dep., Defs.' Ex. 121, 173:21–25.)

sketches reflect the bulbous, “Mickey Mouse” ear shaped tabs reminiscent of the claimed design. Rather, the sketches depict the basic outline of an introducer sheath with a rectangular handle and slightly tapered, rounded-off tabs. Thus, I conclude that these sketches do little to assist Defendants in overcoming the presumption that Plaintiff invented the claimed design.

I also find Gillespie’s claim that these sketches came from his own mind to be incredible. (Gillespie Tr. Dep., 65:24–66:4.) Prior to being hired by Xentek, Gillespie had no experience designing tearaway introducer sheath handles. (Gillespie Tr. Dep., 180:1–6.) Gillespie also had no prior experience with design patents or aesthetic design. (Id. at 218:19–22.) Gillespie admitted that he relied on Eddings’s input as well as other existing introducer sheath products to create the November 9, 1998 sketches. (Gillespie Tr. Dep., 56:6–16, 180:7–18, 194:13–24, 195:10–14.) Thus, I conclude that it was Eddings who directed Gillespie to prepare the sketches at issue.

But Eddings himself had only an architecture degree and no experience in manufacturing tearaway introducer sheath products before he met with Plaintiff to discuss a new introducer sheath design. (N.T., Vol. 4, 6:24–7:2, 59:25–61:8, 67:18–22.) In fact, at the time of the August 1998 meeting with Plaintiff, Eddings and Galt Medical did not have a tearaway introducer sheath in production. (Id. at 67:18–22.) And neither Eddings’s company, Xentek, which was later formed to make the tearaway introducer sheath product, nor Eddings’s other company, Galt Medical, had the capability to make an introducer sheath product. (Id. at 61:19–20, 62:12–63:22.)

Despite Eddings own lack of experience with these products, Eddings directed Gillespie regarding the aesthetics of the tearaway introducer hub and directed all aspects of the development process related to design. (Id. at 32:13–22, 42:6–8.) As Gillespie admitted, Eddings may have been influenced by others outside of the company regarding which features were important or desirable for the introducer sheath product. (Id. at 45–46.) Gillespie explicitly acknowledged that he was

unaware of any meetings that Eddings had with Plaintiff before Xentek was formed and before Gillespie made the November 9, 1998 drawings. (Id. at 183:4–9, 243:14–17; Pl.’s Pretrial Memo., Stipulation No. 5, at 7.)

Thus, Gillespie was unaware of the meeting between Eddings and Plaintiff at Plaintiff’s home in August 1998, where Plaintiff first disclosed his idea for a new introducer sheath handle design. Gillespie was also unaware that Eddings signed an NDA on behalf of Galt Medical at this meeting before Plaintiff discussed his introducer sheath handle design. Eddings’s testimony at trial corroborated that this meeting occurred, that he and Plaintiff discussed Plaintiff’s product, and that he signed a non-disclosure agreement at Plaintiff’s request before discussing Plaintiff’s product. (N.T., Vol. 4, 67:12-72:8.)

Moreover, Plaintiff, who had years of experience in selling and manufacturing introducer sheath kits and who had witnessed thousands of catheter insertions using these devices, told Eddings in August 1998 that he had been working with a company, Prepco, to manufacture his introducer sheath design. This relationship with Prepco is corroborated, in part, by a drawing of an introducer sheath handle design prepared by Prepco at Plaintiff’s direction in December 1997. (Defs.’ Ex. 17(I).) Plaintiff told Eddings that he was far along into his relationship with Prepco and that he had actually received a prototype of his design from Prepco. Although it resembled his design, Plaintiff said that Prepco’s prototype was not exactly what he wanted. Plaintiff told Eddings that he wanted to manufacture an introducer sheath with bigger, rounded handles that were upswept with notches in either side. Plaintiff also wanted the introducer sheath handle to have a funnel entrance. Eddings told Plaintiff that Galt Medical could manufacture his design, and Plaintiff was invited to Galt’s facility in Dallas, Texas to meet with Eddings.

Based on all of this history, I agree with Plaintiff that Eddings's ideas regarding the introducer sheath handle design were originally conceived by Plaintiff and first discussed with Eddings when they met in August 1998. I also find that Eddings subsequently communicated Plaintiff's ideas to Gillespie as his own without Gillespie knowing that they were, in fact, conceived by Plaintiff.

The Gillespie Memorandum Regarding the November 12, 1998 Meeting Between Plaintiff, Eddings, and Gillespie

Gillespie's memorandum, allegedly memorializing the November 12, 1998 meeting between Plaintiff, Eddings, and Gillespie, also fails to establish that Eddings and Gillespie invented the claimed design. Gillespie drafted the memorandum from his own notes and dated the memorandum December 4, 1998, over three weeks after the meeting occurred. (Defs.' Ex. 17(E).) Apart from a handful of specific references to individuals, a majority of the discussion of the desirable attributes of the introducer sheath product in this memorandum are not attributed to any one individual at the meeting. One of the few ideas attributed to someone is, in fact, related to the size of the introducer sheath handle, which Gillespie credited to Plaintiff and characterized as a design consideration.¹⁴

The Initial Prototype Introducer Sheath and the Subassembly Drawing Prepared by Gillespie on August 6, 1999

After the November 12, 1998 meeting and presumably due to Gillespie's lack of experience in designing introducer sheath products, Gillespie requested certain information from Plaintiff,

¹⁴ Although Gillespie does not attribute it to a specific individual, the memorandum states that the sheath hub should have a "funneled entrance." (Defs.' Ex. 17(E) at 2.) Gillespie could not remember who came up with the idea for this feature. (Gillespie Tr. Dep., 106:9–14.) But I note that it is Plaintiff who consistently referred to the entrance as "funneled," whereas Gillespie used the term "conical port" to describe this feature. (See, e.g., N.T., Vol. 1, 91:23–93:6; N.T., Vol. 2, 13:18–14:19; id. at 106:9–14.)

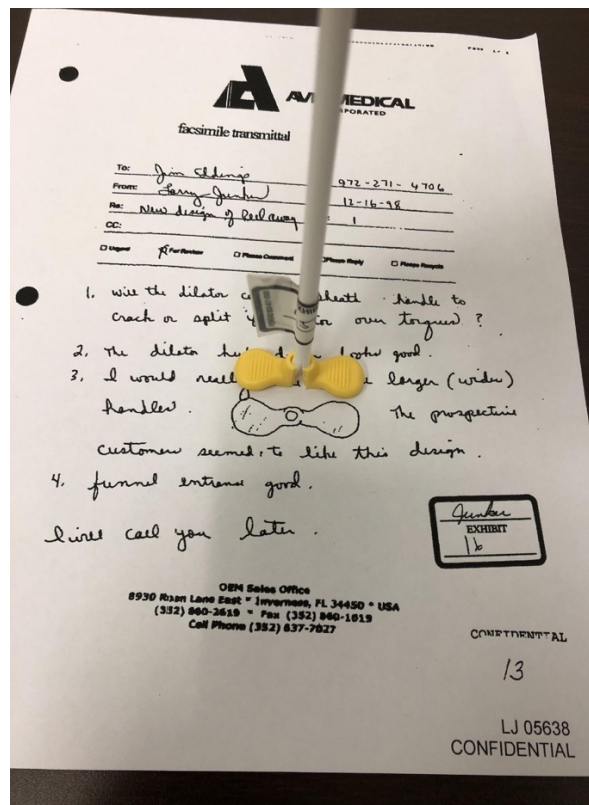
including prior art patents and sample introducer sheath products, that Gillespie needed for what he characterized as “***our*** Tear-away Sheath & Dilator product development program.” (Defs.’ Ex. 17(L) (emphasis added).) Plaintiff provided Gillespie with this information and soon after received a prototype.

Defendants assert that this prototype showed the introducer sheath handle as depicted in Gillespie’s November 9, 1998 drawings, thus corroborating Gillespie’s inventorship of the claimed design. While it is true that the tabs on the prototype handle were similar to the November 9, 1998 drawings, like these drawings, the prototype did not reflect the large, wide, “Mickey Mouse” ear tabs that Plaintiff had envisioned and that were included in the final design of the product. Plaintiff relayed these critiques in a fax to Eddings, stating that he liked certain aspects of the prototype but “would really like to see larger (wider) handles.” (Pl.’s Ex. 11.) Plaintiff also provided a rough sketch in the fax of the type of handle shape he desired. Gillespie himself admitted that the prototype did not have the same ear shape as the final product and that, after Plaintiff sent the fax to Eddings, Eddings directed Gillespie to change the design and enlarge the ears. (Gillespie Tr. Dep., 198:12–17, 205:5–21.) Gillespie characterized Plaintiff’s sketch as a general depiction of the desired handle shape. (*Id.* at 113:1–13.) Eddings never told Gillespie that this change was suggested by Plaintiff. (*Id.* at 205:22–24; 206:2–21.)

After Plaintiff suggested these changes to the prototype, Gillespie drew a subassembly drawing of the introducer sheath product, reflecting the larger, wider tabs. (Defs.’ Ex. 17(N).) Defendants assert that this drawing was created during a one-on-one meeting between Eddings and Gillespie and corroborates their inventorship claim. Yet, when asked at trial who contributed to the design reflected in this drawing, Gillespie acknowledged that Plaintiff had contributed the “propeller shape” of the tabs or “the bulbous shape, sort of hourglass shape in Figure 7 in which

the handles take a sort of circular shape in the exterior into the extremities of the handle.” (*Id.* at 209:20–210:4; 133:22–25, 133:22–25.) In short, Gillespie admitted that Plaintiff conceived the “Mickey Mouse” ear-shaped tabs included in this drawing.

In addition, when Plaintiff received the final prototype of the introducer sheath handle design, which was created using the subassembly drawing, he said that he was excited because all of the features of his design were included. As shown below, and as Plaintiff demonstrated at trial, the finished prototype was nearly identical, in both size and shape, to Plaintiff’s sketch of the desired handle shape design included in his fax to Eddings:



(*See* N.T., Vol. 2, 34:24–36:2.) For all of these reasons, I find that the initial prototype introducer sheath and subassembly drawing also do little to assist Defendants in meeting their significant burden on inventorship.

The ‘914 Patent – Gillespie’s Utility Patent

Finally, Defendants point to the Gillespie Patent as evidence corroborating Gillespie and Eddings’s inventorship claim. This utility patent was, as Gillespie testified, “intended to cover the locking mechanism that was used in [Xentek’s] product.” (Gillespie Tr. Dep at 184:25–185:2.) Although Defendants claim that Plaintiff acquired the drawings submitted in the application for the Gillespie Patent from Gillespie and then used those same drawings to apply for the D’839 Patent a month later, Gillespie admitted that his patent and the D’839 Patent have different drawings. (*Id.* at 186:8–12.) Gillespie testified that the drawings he sent to Plaintiff were not the same drawings used in the D’839 Patent and that he thought the drawings in the D’839 Patent were likely prepared by a patent draftsman. (*Id.* at 28:1–15, 229:7–17.) Gillespie also admitted that his utility patent was different from Plaintiff’s design patent because the locking mechanism was a functional aspect of the product and was not intended to claim the handle or ornamental features of the product. (*Id.* at 185:3–10, 186:4–7, 215:25–216:19.)

iii. Conclusions on Inventorship

In sum, based on my analysis of all evidence regarding the conception of the D’839 Patent, I conclude that Defendants have failed to contradict or otherwise undermine the evidence of conception credibly presented by Plaintiff. In fact, the documents relied on by Defendants are consistent with Plaintiff’s description of the inventive process. After conceiving the claimed design, Plaintiff relied on the “services, ideas, and aid” of Gillespie and Eddings in the process of perfecting that design and reducing it to practice. This reliance on Gillespie and Eddings does not strip Plaintiff of the right to the D’839 Patent and, most importantly, does not make Gillespie and Eddings co-inventors. *Hoop*, 279 F.3d at 1007–08 (finding that “merely refin[ing] and perfect[ing]” an invention did not make one a joint inventor); *see also Ethicon, Inc.*, 135 F.3d at

1460 (reasoning that a person does not become a joint inventor by “merely assisting the actual inventor after conception of the claimed invention”).¹⁵

After weighing the evidence of inventorship presented by Defendants and Plaintiff at trial and assessing the credibility of relevant witnesses, I conclude that Defendants have failed to prove by clear and convincing evidence that Eddings and Gillespie invented the claimed design. Thus, upon consideration of Defendants’ claim that Plaintiff was not the first and sole inventor of the D’839 Patent, I find in favor of Plaintiff.

2. Inequitable Conduct

Inequitable conduct is an equitable defense to patent infringement. Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1285 (Fed. Cir. 2011). If proved, it bars enforcement of the entire patent. Id. Because the doctrine carries such a severe penalty, it is generally only applied where the patentee’s misconduct led to the unwarranted issuance of the patent. Id. at 1292. To establish inequitable conduct, the accused infringer must prove by clear and convincing evidence that the patentee “(1) misrepresented or omitted information material to patentability, and (2) did so with specific intent to mislead or deceive the PTO.” Ohio Willow Wood Co. v.

¹⁵ I also reject Eddings and Gillespie’s claim of conception because of the bias and credibility issues raised by their trial testimony. For example, Eddings’s claim that he is the true inventor is inherently biased, but it also biased by the fact that a jury in a prior lawsuit found Eddings and his companies, Xentek and Galt Medical, to have infringed the D’839 Patent. As a result of this jury verdict, Eddings, Xentek, and Galt Medical paid Plaintiff over \$800,000. (N.T., Vol. 4, 51:23–52:10.) And Gillespie, although not named in Plaintiff’s previous lawsuit, testified at that trial regarding inventorship. But Gillespie did not recall that testimony, even after being shown a copy of the trial transcript. (Gillespie Tr. Dep., 179:3–6, 188:15–25.) Eventually, when Gillespie’s recollection was refreshed by subsequent exhibits, he acknowledged that in the previous lawsuit, he never claimed that he or Eddings were co-inventors of the ornamental features of Plaintiff’s design patent. (Id. at 216:23–217:13; 242:8–243:9.) Yet, now, over a decade later, he makes such a claim. I find this admission to be fatal to Gillespie’s credibility and the credibility of his claim that he invented the design in the D’839 Patent.

Alps South, LLC, 735 F.3d 1333, 1344 (Fed. Cir. 2013) (quoting In re Rosuvastatin Calcium Patent Litig., 703 F.3d 511, 519 (Fed. Cir. 2012)).

Here, Defendants argue that they have presented clear and convincing evidence to prove that Plaintiff intentionally made a material misrepresentation to the PTO, by naming himself the first and sole inventor of the design in the D’839 Patent application, “while using drawings that he knew were not created by him, but by Eddings and Gillespie.” (Defs.’ Br. ¶ 112.) Defendants also contend that Plaintiff made a material misrepresentation to the PTO “when he submitted two separate declarations that he was the first and sole inventor of the D’839 Patent.” (Id. ¶ 113.)

Because I have concluded that Plaintiff is the first and sole inventor of the D’839 Patent, Plaintiff could not have misled the PTO regarding inventorship. Thus, any defense or counterclaim regarding Plaintiff’s inequitable conduct must fail.

3. Anticipation

Under 35 U.S.C. § 102, a design patent may be invalidated as not novel if it was anticipated by the prior art. Int’l Seaway Trading Corp. v. Walgreens Corp., 589 F.3d 1233, 1238 (Fed. Cir. 2009). Before the enactment of the American Invents Act (“AIA”), under § 102, a person was entitled to a patent unless:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, ***before the invention*** thereof by the applicant for patent, or (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, ***more than one year prior to the date of the application for patent*** in the United States, or . . . (e) the invention was described in—(1) an application for a patent, published under section 122(b),¹⁶ by another filed in the United States ***before the invention*** by the applicant for patent . . .

¹⁶ For the first time, the PTO began publishing patent applications filed on or after November 29, 2000, eighteen months after the effective filing date of the application. “USPTO Will Begin Publishing Patent Applications,” The United States Patent and Trademark Office (Nov. 27, 2000), <https://www.uspto.gov/about-us/news-updates/uspto-will-begin-publishing-patent-applications>. Thus, the Gillespie Patent application would not have been published at the time Plaintiff applied

35 U.S.C. § 102(a)–(b), (e)(1) (pre-AIA) (emphasis added).

Thus, before the AIA’s changes to § 102, “the United States typically gave priority to the first to invent.” Mastad Eng’g, Inc. v. U.S. Patent and Trademark Office, 756 F.3d 1366, 1368 (Fed. Cir. 2014). “Priority of invention goes to the first party to reduce an invention to practice unless the other party can show that it was the first to conceive of the invention and that it exercised reasonable diligence in later reducing that invention to practice.” See, e.g., Barry v. Medtronic, Inc., 914 F.3d 1310, 1332 (Fed. Cir. 2019). A reduction to practice can either be “a constructive reduction to practice, which occurs when a patent is filed, or an actual reduction to practice.” Cooper v. Goldfarb, 154 F.3d 1321, 1327 (Fed. Cir. 1998). In order to establish an actual reduction to practice, “the inventor must prove that: (1) he constructed an embodiment or performed a process that met all of the limitations of the interference count; and (2) he determined that the invention would work for its intended purpose.” Id.

After the AIA was enacted, under § 102, a person is entitled to a patent unless:

(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the ***effective filing date***¹⁷ of the claimed invention; or (2) the claimed invention was described in a patent . . . or an application for patent published or deemed published under section 122(b), in which the patent or application . . . names another inventor and was effectively filed before the ***effective filing date*** of the claimed invention.

for the D’839 Patent, not only because patent applications were not published by the PTO in January 2000, but also because the Gillespie Patent application was only filed approximately a month before the D’839 patent application.

¹⁷ “The term ‘effective filing date’ for a claimed invention in a patent or application for patent means . . . the actual filing date of the patent or the application for the patent containing a claim to the invention . . . the filing date of the earliest application for which the patent or application is entitled” 35 U.S.C. § 100(i)(1).

35 U.S.C. § 102(a) (emphasis added). Thus, the AIA adopted the “first-inventor-to-file” principle for determining priority among patents and patent applications. Under this principle, “priority will go to the first inventor to file a patent application.” Mastad Eng’g, Inc., 756 F.3d at 1368.

This “first-to-file” principle, however, does not apply to any patent application filed *before March 16, 2013*. Manual of Patent Examining Procedure (“MPEP”) 2159.01 (9th ed. Rev. June 2020) (emphasis added); *see also, e.g., GS Cleantech Corp. v. Adkins Energy LLC*, 951 F.3d 1310, 1318 n.7 (Fed. Cir. 2020) (“Congress amended 35 U.S.C. § 102 when it passed the Leahy-Smith America Invents Act (‘AIA’), and AIA § 4(e) made those changes applicable to ‘any patent application that is filed on or after’ September 16, 2012. Because the application that led to the Patents-in-Suit was filed before September 16, 2012, pre- AIA § 102 applies.”).

Because Plaintiff applied for the D’839 Patent on February 7, 2000, the alleged invalidity of the D’839 Patent based on anticipation by the prior art is governed by pre-AIA standards under § 102, i.e. the first-to-invent principle.

If prior art, as defined by § 102, is identified, the test for anticipation of a design patent is identical to the test for infringement. Int’l Seaway, 589 F.3d at 1240 (explaining that the tests for infringement and anticipation are identical because “[t]hat which infringes, if later, would anticipate, if earlier” (quoting Peters v. Active Mfg. Co., 129 U.S. 530, 537 (1889))).

Here, Defendants argue that the D’839 Patent is anticipated by the Gillespie Patent, issued to Richard Gillespie on January 8, 2002, and is therefore invalid. (See Defs.’ Ex. 104.) Defendants assert that Gillespie’s patent application, dated January 13, 2000, was filed approximately a month before Plaintiff filed the application for the D’839 patent. Defendants contend that the Gillespie Patent is virtually identical to the D’839 Patent, creating the same overall visual impression. (Defs.’ Br. ¶ 10 (citations omitted).) Defendants also point out that Plaintiff sued Eddings and Xentek in

2003, claiming that the Gillespie Patent contained his invention. Defendants argue that based on this prior lawsuit, “[b]ecause ‘that which infringes, if later, would anticipate, if earlier,’” Plaintiff has admitted that the Gillespie Patent, which is prior art, anticipates the D’839 Patent. (Defs.’ Br. ¶ 122.)

Plaintiff responds that because the D’839 Patent was pre-AIA, (1) the D’839 Patent has priority over the Gillespie Patent because Plaintiff was the first to invent the design claimed in the D’839 Patent and (2) the Gillespie Patent does not qualify as prior art because the patent application was filed only a month before the D’839 Patent application. Plaintiff also points out that Defendants have failed to overcome the deference due to the PTO because, when the PTO reexamined the D’839 Patent, it found the Gillespie patent to be non-enabling art and not anticipatory.

I agree with Plaintiff’s position. The D’839 Patent has priority over the Gillespie Patent because Plaintiff was the first to conceive the design claimed in the D’839 Patent and exercised reasonable diligence in later reducing that design to practice. As discussed above in Section II.B.1, from Plaintiff’s conception of the design between 1996 and 1997 to his application for a patent one month after Gillespie applied for the Gillespie Patent, Plaintiff diligently sought to locate a company capable of creating his introducer sheath design—first, Prepro and then Galt Medical and Xentek. See also Medtronic, 914 F.3d at 1332. It was while Plaintiff worked with Gillespie and Eddings to reduce his design to practice that Gillespie filed for a patent without Plaintiff’s knowledge, using drawings that embodied the design that Plaintiff had conceived. Once Plaintiff learned that Gillespie had filed for a patent, he promptly applied for the D’839 Patent. Based on this evidence, Plaintiff has credibly shown that he was the first to conceive the claimed design and

that he exercised reasonable diligence in reducing the claimed design to practice. Thus, I conclude that the Gillespie Patent is not prior art, and Defendants have failed to prove anticipation.¹⁸

4. Obviousness

Under 35 U.S.C. § 103, a design patent may be invalidated if its claims are obvious in light of the prior art. Titan Tire Corp. v. Case New Holland, Inc., 566 F.3d 1372, 1380 (Fed. Cir. 2009). Section 103, pre-AIA, which, for the reasons stated above, applies here, provides that “[a] patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious *at the time the invention was made* to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103(a) (pre-AIA) (emphasis added); MPEP 2159.01 (9th ed. Rev. June 2020); see also Redline Detection, LLC v. Star Envirotech, Inc., 811 F.3d 435, 449 n.7 (Fed. Cir. 2015).

“In the design patent context, the ultimate inquiry under section 103 is whether the claimed design would have been obvious to a designer of ordinary skill who designs articles of the type involved.” Durling v. Spectrum Furniture Co., 101 F.3d 100, 103 (Fed. Cir. 1996); see also Spigen Korea Co., Ltd. v. Ultraproof, Inc., 955 F.3d 1379, 1383 (Fed. Cir. 2020). To determine obviousness, the factfinder follows a two-step analysis:

[F]irst, “one must find a single reference, a something in existence, the design characteristics of which are basically the same as the claimed design”; second, “[o]nce this primary reference is found, other [secondary] references may be used

¹⁸ A patent would also be invalid if the claimed invention was “patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, *more than one year prior to the date of the application for patent* in the United States.” 35 U.S.C. § 102(b) (pre-AIA) (emphasis added). But the Gillespie Patent was not applied for or issued more than a year before Plaintiff applied for the D’839 Patent. Therefore, Defendants’ anticipation defense also fails under 35 U.S.C. § 102(b), pre-AIA. See Monsanto Tech. LLC v. E.I. DuPont de Nemours & Co., 878 F.3d 1336, 1342–43 (Fed. Cir. 2018).

to modify it to create a design that has the same overall visual appearance as the claimed design.”

High Point Design LLC v. Buyers Direct, Inc., 730 F.3d 1301, 1311 (Fed. Cir. 2013) (quoting Durling, 101 F.3d at 103).

When looking for a primary reference under the first step, I must “(1) discern the correct visual impression created by the patented design as a whole; and (2) determine whether there is a single reference that creates ‘basically the same’ visual impression.” Durling, 101 F.3d at 103; see also High Point Design, 730 F.3d at 1311. I “may determine almost instinctively whether the two designs create basically the same visual impression,” as long as I provide the reasoning behind that determination. MRC Innovations, Inc. v. Hunter Mfg., LLP, 747 F.3d 1326, 1332 (Fed. Cir. 2014). For designs to be “basically the same,” they “cannot have ‘substantial differences in the[ir] overall visual appearance[s].’” Spigen Korea Co., Ltd., 955 F.3d at 1383 (quoting Apple, Inc. v. Samsung Elecs. Co., Ltd., 678 F.3d 1314, 1330 (Fed. Cir. 2012)) (alterations in original). If “major modifications” are needed to make the reference look like the claimed design, the two designs are not “basically the same.” Id. (quoting In re Harvey, 12 F.3d 1061, 1063 (Fed. Cir. 1993)). Slight design differences do not, however, preclude a finding that designs are “basically the same.” Id.

Additionally, the secondary references under step two “must be ‘so related [to the primary reference] that the appearance of certain ornamental features in one would suggest the application of those features to the other.’” Titan Tire Corp., 566 F.3d at 1381.

Here, Defendants argue that the Gillespie Patent is a proper primary prior art reference because the Gillespie Patent and the D’839 Patent create a nearly identical visual impression. Defendants also identify the “Jamshidi, Groshong, Bley, and Gisselberg Patents” as secondary prior art references, “each relating to insertion of a needle or catheter into the human body and each claiming the same basic structure as the Gillespie Patent.” (Defs.’ Br. ¶ 130.)

Plaintiff responds that the Gillespie Patent is not prior art by definition because the Gillespie Patent application was filed a month before the D’839 Patent application was filed. Plaintiff also argues that because Plaintiff was the first to invent, the D’839 Patent has priority over the Gillespie Patent. In response to Defendants’ alleged secondary prior art references, Plaintiff argues that the “Gisselberg Patent” merely shows ribs on the handle but otherwise shows a flat rectangular handle, “as with Groshong” and that “both only show features common to introducers and bear little relationship to the ornamental features in the ‘839 patent.” (Pl.’s Br. at 23.) Finally, Plaintiff argues that the commercial success of the patented design when sold at Galt Medical from 2002 to 2003 and Defendants’ use of the rounded ear design after receiving notice of the injunction and losing Galt Medical as a supplier are both factors supporting non-obviousness.

I agree with Plaintiff’s position on obviousness for several reasons. First, as set forth in Section II.B.3, I have concluded that the D’839 Patent has priority over the Gillespie Patent because Plaintiff was the first to invent to claimed design. Thus, the Gillespie Patent cannot serve as a proper primary prior art reference at the time the claimed design was “made” because the Gillespie Patent is not prior art. 35 U.S.C. § 103(a) (pre-AIA). Defendants have not identified another primary prior art reference.

Second, even applying the primary prior art reference standard to the other prior art identified by Defendants as secondary references, I find that the design characteristics of these prior inventions do not evoke “basically the same” visual impression as the D’839 Patent.

For instance, United States Patent Number 5,885,217 (the “Gisselberg Patent”), United States Patent Number 4,772,266 (the “Groshong Patent”), and United States Patent Number 5,762,630 (the “Bley Patent”) fail to depict the most identifiable design characteristic and a key aspect to the overall visual impression of the design of the D’839 Patent—the rounded, bulbous or

“Mickey Mouse” ear-shaped tabs. (See Defs.’ Exs. 8, 9, 11.) The Groshong and Gisselberg Patents both depict small, squared-off tabs and a rectangularly-shaped handle. The Bley Patent shows narrow, up-swept, horn-like tabs on the handle.

Although United States Patent Number 3,626,524 (the “Jamshidi Patent”) depicts small, circular tabs and a rounded handle, I do not find that the Jamshidi Patent and the claimed design create basically the same visual impression. The invention claimed by the Jamshidi Patent lacks the “Mickey Mouse” ear shaped tabs that are larger and wider in proportion to the remainder of the handle as well as other major aspects of the overall visual impression of the D’839 Patent’s claimed design, such as the upswept handle, the ribs, and a cone-shaped hub, let alone a hub of any kind.

Furthermore, the essential inquiry for obviousness is whether the claimed design would have been obvious to “a designer of ordinary skill who designs articles of the type involved.” Durling, 101 F.3d at 103. And, although Meyst testified that a biopsy needle is a medical device with components similar to the tearaway introducer, I am not persuaded that a biopsy needle, the device claimed by the Jamshidi Patent, is the same type of article as the D’839 Patent’s introducer sheath for purposes of my obviousness analysis.

Finally, a presumption of the D’839 Patent’s validity applies here because the Jamshidi Patent was disclosed to and considered by the PTO when it reexamined the D’839 Patent and, ultimately, upheld its validity. PowerOasis, Inc. v. T-Mobile USA, Inc., 522 F.3d 1299, 1304 (Fed. Cir. 2008) (quoting Am. Hoist & Derrick Co. v. Sowa & Sons, 725 F.2d 1350, 1360 (Fed. Cir. 1984), abrogated on other grounds by Therasense, Inc. v. Becton, Dickinson and Co., 649 F.3d 1276 (Fed. Cir. 2011)). Defendants have failed to satisfy the added burden of overcoming this deference to the PTO. For all of these reasons, Defendants’ obviousness defense fails.

5. Primarily Functional Design

Design patents can be issued for “any new, original and ornamental design for an article of manufacture.” 35 U.S.C. § 171. Though articles of manufacture necessarily provide a utilitarian function, design patents only protect the ornamental designs of the articles. Ethicon-Endo Surgery, 796 F.3d at 1328. A design patent cannot be issued for designs that are “essential to the use of an article.” Id. “[D]esigns [are] essential to the use of an article when the claimed design is ‘dictated by’ the use or purpose of the article.” Id. (quoting L.A. Gear, Inc. v. Thom McAn Shoe Co., 988 F.2d 1117, 1123 (Fed. Cir. 1993)). Design patents for primarily functional designs rather than ornamental designs are therefore invalid. Id.

As with other invalidity defenses, the alleged infringer must prove that a patent is invalid on grounds of functionality by clear and convincing evidence. Ethicon Endo-Surgery, Inc. v. Covidien, Inc., 796 F.3d 1312, 1328 (Fed. Cir. 2015). The Federal Circuit has “described as ‘stringent’ [the clear and convincing] standard as it applies to invalidating design patents on grounds of functionality.” Id. (quoting Rosco, Inc. v. Mirror Lite Co., 304 F.3d 1373, 1378 (Fed. Cir. 2002)).

When determining whether the claimed design is primarily functional, the court must not confuse the “function of the article itself” with the “‘functionality’ of the design of the article.” Id. In other words, a claimed design is “not invalid as functional simply because the ‘primary features’ of the design could perform functions.” Id. at 1329. Further, the functionality of individual design elements is not the relevant focus—instead, the court must consider the “overall appearance of the article,” viewing the claimed design in its entirety. Id.

Though no settled test exists for determining whether a claimed design is dictated by its function, the Federal Circuit often focuses on “the availability of alternative designs as an

important—if not dispositive—factor” Id. at 1329–30. If several designs can achieve the article’s function, the claimed design is more likely to be ornamental and the patent valid. Id. at 1330.

Defendants argue that, because each element of the claimed design is dictated by function, the D’839 Patent is invalid. Defendants assert that:

At trial, Junker stated that the size of the “Mickey Mouse” ear-shaped handles in the D’839 Patent was intended to allow space for users to grip the handles. The round shape was designed to prevent the snagging and tearing of gloves worn by the device user. Relatedly, Junker asserted that the ribs on the “ears” prevent the user’s fingers from slipping. The backswept wings allow for increased leverage when pressure is applied in the process of snapping the hub after insertion. Junker testified that the notches and funnel entrance in the hub were designed to “allow the catheter to be able to slide in without having to find a little tiny hole.” He also testified that the grooves inside the notches “allow the . . . sheath to peel easily.”

(Defs.’ Br. ¶ 6 (citations omitted).)

Although Plaintiff acknowledged the functionality of his handle design, he testified that a new design of the introducer sheath product would improve its appearance and make it easier to sell. (N.T., Vol. 2, 5:3–12.) Plaintiff explained that his “improved design” was going to be “eye catching” for customers. (Id. at 5:14–18.) Simply because the design of Plaintiff’s introducer sheath handle has function does not make the design primarily functional. Alternative designs for introducer sheath handle tabs were available as evidenced by the multiple prior art references introduced by the parties. (Pl.’s Exs. 3, 24, 41; Defs.’ Exs. 8, 9, 11.) Moreover, these alternative designs or alternatively shaped handles were able to achieve the same function.

The testimony of Defendants’ own design expert, Meyst, confirms this point. Meyst affirmed that the function of the handle tabs could be accomplished by “any number of shapes” and that, in fact, there were many ways “to have tabs on an introducer sheath handle” as shown by the prior art. (N.T., Vol. 7, 83:3– 11.) Meyst further acknowledged that introducer sheath handle

tabs do not need to be rounded in order to function; the tabs of the handle could be square or rectangular and still perform the same function. (Id. at 83:20–23, 85:14–19.) In addition, Michael Anstett, a former employee of Defendant MedComp, testified that “the handle shape” was of no consequence to a “successful insertion.” (N.T., Vol. 5, 19:24–20:5.) He also testified that the introducer handle shape is not dictated by its function and that a particular shape and size of the handle is not required to be functional. (Id. at 41:23–43:8.)

Given the record before me, I find that Defendants have failed to prove by clear and convincing evidence that the claimed design is primarily functional.

C. Damages

Having concluded that the Accused Products infringe the D’839 Patent and that Defendants have failed to prove invalidity, I set forth below the appropriate damages award.

Pursuant to 35 U.S.C. § 289, “[w]hoever during the term of a patent for a design, without license of the owner, (1) applies the patented design, or any colorable imitation thereof, to any article of manufacture for the purpose of sale, or (2) sells or exposes for sale any article of manufacture to which such design or colorable imitation has been applied shall be liable to the owner to the extent of his total profit, but not less than \$250” The “total profit” referenced in § 289 is “all of the profit made from the prohibited conduct, that is, from the manufacture or sale of the article of manufacture to which [the patented] design or colorable imitation has been applied.” Samsung Elecs. Co., Ltd. v. Apple Inc., 137 S. Ct. 429, 434 (2016) (internal quotation marks omitted).

Thus, calculating damages under § 289 requires two steps: (1) identifying the article of manufacture and (2) calculating the total profits that the infringer made from that article of manufacture. Id. The plaintiff bears both the burden of production and persuasion in identifying

the article of manufacture and total profit on the sale of that article. Apple Inc. v. Samsung Elecs. Co. Ltd., No. 11-1846, 2017 WL 4776443, at *13–14 (N.D. Cal. Oct. 22, 2017). If the plaintiff satisfies its burden on these issues, then the burden shifts to the defendant to produce evidence of an alternative article of manufacture and any deductible expenses. Apple Inc., 2017 WL 4776443, at *13–14; Henry Hanger & Display Fixture Corp. of Am. V. Sel-O-Rak Corp., 270 F.2d 635, 643 (5th Cir. 1959) (“The burden of establishing the nature and amount of [deductible costs], as well as their relationship to the infringing product, is on the defendants.”).

1. Article of Manufacture

In Samsung Electronics Co., Ltd. v. Apple Inc., the United States Supreme Court addressed the scope of the term “article of manufacture” in § 289: “The only question we resolve today is whether, in the case of a multicomponent product, the relevant ‘article of manufacture’ must always be the end product sold to the consumer or whether it can also be a component of that product.” 137 S. Ct. at 434. As reasoned by the Supreme Court, the term “article of manufacture” has broad meaning; it is “simply a thing made by hand or machine.” Id. at 434–5. Thus, the term is “broad enough to embrace both a product sold to a consumer and a component of that product, whether sold separately or not.” Id. at 436. Although the parties in Samsung asked the Supreme Court to determine the article of manufacture for the design patents at issue in that case, the Court declined to do so and remanded to the Federal Circuit for further proceedings. See id. On remand, the Federal Circuit held that the trial court was in the best position to evaluate the parties’ arguments regarding the proper test for determining article of manufacture. Apple Inc. v. Samsung Elecs. Co., Ltd., 678 F. App’x 1012, 1014 (Fed. Cir. Feb. 7, 2017).

On remand from the Federal Circuit, the district court identified the following four factors relevant to the article of manufacture determination under § 289:

1. The scope of the design claimed in the plaintiff's patent, including the drawing and written description;
2. The relative prominence of the design within the product as a whole;
3. Whether the design is conceptually distinct from the product as a whole; and
4. The physical relationship between the patented design and the rest of the product, including whether the design pertains to a component that a user or seller can physically separate from the product as a whole, and whether the design is embodied in a component that is manufactured separately from the rest of the product, or if the component can be sold separately.

Apple Inc., 2017 WL 4776443, at *19.

The following question has emerged since the Supreme Court's decision in Samsung: must the "article of manufacture" for patentability purposes under 35 U.S.C. § 171¹⁹ be the same "article of manufacture" for purposes of calculating damages under § 289? The district court's decision in Apple supports a finding that a patentable "article of manufacture" under § 171 need not be the same as an "article of manufacture" for purposes of § 289. See Apple, Inc., 2017 WL 4776443, at *11–12. That court concluded that the scope of the design claimed in a patent, including the drawings and written description, is but one factor in the article of manufacture test. See id. Thus, although necessary to determine patentability, the scope of the claimed design is not dispositive in determining the appropriate article of manufacture under a § 289 disgorged profits analysis. See id.

The district court in Luxembourg v. Home Expressions Inc., No. 17-4079, 2018 WL 340036, at *7 (D.N.J. Jan. 8, 2018), had a different interpretation. That court reasoned that an

¹⁹ "Whoever invents any new, original and ornamental design for an article of manufacture may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 171.

“article of manufacture” for purposes of § 289 is coextensive with the scope of the patent’s protections under § 171. See Luxembourg, 2018 WL 340036, at *7 (explaining that § 289 “should not be read as creating a remedy that is broader than the right” to patent protection under § 171), aff’d on other grounds by 938 F.3d 1334 (Fed. Cir. 2019).

Without a clear directive from the Federal Circuit on this issue²⁰ and based on the parties’ agreement that I evaluate the four factors set forth in Apple in order to determine the relevant article of manufacture,²¹ I will apply the district court’s Apple test to my determination of damages. My application of that test assumes, based on the precedent discussed above, that the relevant article of manufacture can either be the full tearaway introducer sheath product sold by Defendants or the handle of that product.

In support of his argument that the relevant article of manufacture is the full introducer sheath product sold by Defendants, Plaintiff asserts that, although Apple finds that the relevant article of manufacture may be something less than the entire saleable unit, Apple does not ask the factfinder to “chop solid objects into pieces based on the claim of the design patent.” (Pl.’s Br. at 26.) Plaintiff explains that while the design of the handle of the introducer sheath may be its most prominently noticeable feature, the handle is merely a feature of the whole, not a distinct item of manufacture or sale or even an article physically separable from the sheath. According to Plaintiff, the handle never exists as a separate physical object since it is formed with the sheath at the time

²⁰ Although the Federal Circuit has never directly addressed the “article of manufacture” issue as it relates to damages under § 289, I recognize that dicta in Advantek Marketing, Inc. v. Shanghai Walk-Long Tools Co., Ltd., could support the district court’s approach in Luxembourg: “Of course, if the accused skeletal structure is only a component of an accused multicomponent product, [the plaintiff] would only be able to seek damages based on the value of the component, not the product as a whole.” 898 F.3d 1210, 1217 n.2 (Fed. Cir. 2018).

²¹ (Defs.’ Br. at ¶ 140; Pl.’s Br. at 25.)

of manufacture. Plaintiff points out that the saleable unit in this case is either an introducer sheath on its own, sometimes sold separately, or a kit of which an introducer is a component. Thus, Plaintiff urges that based on the Apple factors, it is reasonable for me to conclude that the appropriate article of manufacture is the whole introducer sheath product sold by Defendants.²²

Defendants respond that the relevant article of manufacture is the handle of the Accused Products, not the introducer sheath as a whole. Defendants argue that the scope of the patent, i.e. the components of the drawings displayed in solid lines as dictated by my Claim Construction Order, requires a finding that the handle is the operative article of manufacture. Defendants point out that the handle is not the prominent feature of the product as a whole—rather, the sharpness of the tip and smoothness of the transition are most prominent. According to Defendants, the handle is conceptually distinct from the product as a whole because the handle may vary in structure, but the sheath itself is relatively consistent in its structure. Finally, Defendants assert that the handle is manufactured separately from the sheath, which is made of different materials altogether and purchased from a third-party vendor.

After weighing the Apple factors and for the following reasons, I conclude that the full introducer sheath product is the relevant article of manufacture for purposes of § 289.

With regard to the first Apple factor, the claimed design in the D'839 Patent is the ornamental design for a handle. This is consistent with my claim construction. I excluded the introducer's sheath from that claim, which appeared in broken lines in Figure 1 of the D'839 Patent.

²² Plaintiff also asserts that until January 15, 2020, on the eve of trial, when Defendants produced the final, revised expert report of their damages expert, Dana Trexler, Defendants had taken the position that the introducer sheath as a whole was the appropriate article of manufacture. As Plaintiff explains, January 15, 2020 was the first time Defendants introduced the theory that the handle of the Accused Products was the appropriate article of manufacture under § 289.

I find that the second Apple factor, the relative prominence of the design within the product as a whole, favors Plaintiff. Defendants contend that the handle is not the most prominent feature of the introducer sheath but rather the sharpness of the tip and the smoothness of the transition between dilator and sheath are most important. For many of the reasons discussed above regarding infringement, I agree with Plaintiff's design expert, Bressler, who concluded that the predominating elements of the design were, first and foremost, the "Mickey Mouse" ear shaped tabs, followed by the ribs on the tabs, and the shape of the hub. These features, which are all part of the handle, are the most prominent of the product as a whole, whereas the sheath and dilator are both relatively simple in structure—one a hollow tube (sheath) and the other a solid tube with a tip that tapers into a point (dilator).

Regarding the third Apple factor, whether the design is conceptually distinct from the product as a whole, I conclude that this factor favors Defendants. The D'839 Patent claims only the design of an introducer sheath's handle. And, as previously discussed regarding invalidity, the handle can vary in shape and size, while the sheath and dilator are relatively consistent in structure.

Finally, I conclude that the fourth Apple factor favors Plaintiff. This factor requires consideration of the physical relationship between the patented design and the rest of the product, including whether the design pertains to a component that a user or seller can physically separate from the product as a whole, and whether the design is embodied in a component that is manufactured separately from the rest of the product, or if the component can be sold separately. Here, the handle of the Accused Products was mechanically bonded with the sheath at manufacturing and was not intended to be physically separated from the product as a whole. The sheath of the Accused Products was manufactured separately from the handle. And, as previously explained, Defendant Martech bought the sheath from a third party, inserted that sheath into the

handle mold, and then melted plastic to make the handle around that sheath, bonding the two parts together at the time the handle was made. Despite the sheath being manufactured separately, the handle was not made separately from the sheath. In other words, Martech did not manufacture handles and then fuse them to sheaths bought from a third party. The handle never existed separately from the sheath. Defendants also did not sell the handle separately; the saleable unit is the whole introducer sheath product.

It is also important to note that in my March 19, 2020 Memorandum Opinion in this case, I excluded any testimony of Defendants' damages expert, Dana Trexler, that relied on the introducer sheath's handle as the relevant article of manufacture. I reasoned in that Opinion that based on the four-factor test in Meyers v. Pennypack Woods Home Ownership Association, 559 F.2d 894, 904–5 (3d Cir. 1977), Trexler's testimony on this issue should be excluded because before January 15, 2020, the eve of trial, Defendants had pursued a damages theory based on profits from the entire introducer sheath. Thus, I found that Plaintiff was prejudiced by the late production of this article of manufacture theory and lacked the ability to cure that prejudice before trial.

After weighing all of the Apple factors, I conclude that the relevant article of manufacture for purposes of calculating Plaintiff's damages under § 289 is the entire introducer sheath product as sold by Defendants because the handle is the predominant feature of the product as a whole, the user cannot physically separate the handle from the sheath, the handle is not manufactured separately from the sheath, and the handle is not sold separately by Defendants.

2. Calculation of Damages

Having identified the relevant article of manufacture, I must next determine the amount of damages to be awarded to Plaintiff. Plaintiff has the burden to prove Defendants' "total profits on

the article of manufacture.” (Pl.’s Br. at 27.) To meet this burden, Plaintiff proposes several approaches for calculating disgorged profits.²³

Plaintiff first argues that he has “met his burden” to prove “total profits” by showing “net sales of the [Accused Products], leaving it to defendants to prove proper deductions.” (Pl.’s Br. at 27.) According to Plaintiff, Defendants’ net sales on the Accused Products total \$19,404,990. I find Plaintiff’s focus on “net sales,” instead of total profits, to be both confusing and misplaced. As noted above, under § 289, Plaintiff may only be awarded Defendants’ “total profit” from the Accused Products. An award of “net sales,” without deducting any costs, would result in a windfall to Plaintiff and fails to reflect the appropriate deductions identified by Defendants.

Apparently recognizing my inability to award net sales, Plaintiff next suggests an award of \$13,985,513 in gross profits, “demonstrating . . . Medcomp profits amounting to \$13,413,098 and Martech profits of \$572,415.” (*Id.*) Plaintiff calculates gross profits by deducting material, labor, and overhead costs from Defendants’ net sales. Plaintiff contends that I must “award all of the profits disclosed, or \$13,985,513,” because “Defendant[s] ha[ve] failed to provide evidence from which to calculate the deduction of profits generated by the sale of non-accused products within the kits.” (Pl.’s Br. at 28.)

I disagree that Plaintiff’s reliance on Defendants’ combined net sales or even total gross profits from the sale of the Accused Products satisfies his burden to prove damages. As Plaintiff acknowledges, he must prove total profits, which means all of the profit made from the manufacture or sale of the article of manufacture to which the patented design has been applied.

²³ I note the Accused Products’ dates of sale, which are relevant to my damages calculation: Martech sold the accused Super Sheath products from February 15, 2010 to December 27, 2013; MedComp sold the accused Super Sheath products from January 15, 2013 to May 6, 2014; Martech sold the accused Valved Tearaway products from July 15, 2009 to March 4, 2014; and MedComp sold the accused Valved Tearaway products from August 25, 2009 to April 23, 2014.

Samsung, 137 S. Ct. at 434; (Pl.’s Br. at 27 (“The recovery of infringer’s ‘total profit’ relates to the profit from the entire infringing good . . .” (quoting Nike, Inc., 138 F.3d at 1441–43).) Plaintiff acknowledges that the “appropriate article of manufacture for kit sales infringement is the component introducer, rather than the entire kit.” (Pl.’s Br. at 26.) Thus, contrary to Plaintiff’s contention, I find that he has the burden to prove not only the total profit from the individual sale of the Accused Products, but also the total profits attributable to the ***introducer sheath component sold in Defendants’ kits***. In other words, proof of the total profits from the entire kit sold by Defendants is insufficient to meet Plaintiff’s burden to prove damages under § 289.

Plaintiff attempts to identify a methodology for determining the amount of profit attributable to the Accused Products sold as part of the kit, suggesting that I attribute twenty-five percent of the total profits from the kits to the introducer sheath component. This percentage is based, in part, on testimony from Timothy Schweikert, Defendants’ President, identifying the introducer sheath as one the “top four” items in the kits. (N.T., Vol. 6, 8:9–22.) Plaintiff also relies on his own testimony regarding a brochure for one of Defendants’ kits to support this percentage of profit. Plaintiff testified that of the dozen or so items listed as included in this kit, the introducer sheath is listed at “number two.” (N.T., Vol. 2, 90:13–24.) Plaintiff claimed that most of the items included in the kit were “convenience items” that cost “next to nothing” to purchase. (Id. at 91:14–21, 93:3–8.) According to Plaintiff, in terms of importance to the profit of the kit, the introducer sheath is “only superseded by the catheter” and attributed forty or fifty percent of the kit’s profit to the introducer. (Id. at 92:18–25.) Based solely on this testimony, Plaintiff contends that I should attribute twenty-five percent of the total kit profit to the introducer sheath. Applying this percentage, Plaintiff asserts that the total profits attributed to the introducer sheath sold in

Defendants' kits was \$3,353,274 and the total profit from Defendants' individually sold introducer sheaths was \$572,415, totaling \$3,925,689 in disgorged profits.

Other than the testimony discussed above, Plaintiff offers no other evidence to support this damages theory. He seeks to apportion profit equally among four items in the kits, but there are many more than four items sold in Defendants' kits. And, beyond the catheter and introducer sheath, Plaintiff fails to identify the remaining two items that form the basis of his proposed percentage of profit. (*Id.* at 91:22–92:1.) Instead, Plaintiff asks me to accept, without evidence, that there are only “one or two other necessary items” sold in the kit, (Pl.'s Br. at 29), and that the many remaining items sold in these kits contribute nothing to their profits. Although there is testimony in the record to support that the introducer sheath is one of the more important items sold in the kits, I agree with Defendants' expert, Trexler, that there is no credible basis for Plaintiff's methodology of attributing twenty-five percent profitability to the introducer sheath. Thus, I find that this theory for attributing profit is both based on insufficient evidence and fails to apply a credible methodology for proving damages.

Defendants' expert, Trexler, who has considerable experience in testifying as a damages expert (Defs.' Ex. 155a), offered a reliable methodology for attributing profit to the introducer sheaths sold in Defendants' kits. Trexler calculated Defendants' total profits from the Accused Products by first removing incremental costs. As stated above, Defendants' gross profits, on which Plaintiff relied and as identified in Defendants' sales spreadsheets, (Defs.' Exs. 156a, 157a, and 158a), were calculated by deducting material, labor, and overhead costs from Defendants' net sales. Trexler also testified that there were other costs that had to be deducted from this gross profit figure, such as sales commissions. Once all reasonable expenses were deducted, Trexler apportioned profit from each of the Accused Products sold in Defendants' kits by identifying the

average profit on each of the Accused Products when sold individually, (Defs.' Ex. 157a), and attributing that profit to every kit in which that Accused Product was sold. (Defs.' Exs. 156a, 158a, and 162).

I agree with Trexler's methodology for calculating damages and, therefore, adopt it. I conclude that the total profit from the accused Super Sheath products during the relevant time period identified above was \$52,901 and the profit from the accused Valved Tearaway products during the relevant time period identified above was \$1,195,009, totaling \$1,247,910 in disgorged profits from Defendants' sale of the Accused Products. (N.T., Vol. 9, 54:13–15; see also Defs.' Ex. 155.)

III. CONCLUSION

For the foregoing reasons, I conclude that Plaintiff has proven by a preponderance of the evidence that the Accused Products infringe the D'839 Patent. I also conclude that Defendants have failed to prove, by clear and convincing evidence, that (1) Plaintiff is not the first and sole inventor of the D'839 Patent; (2) Plaintiff engaged in inequitable conduct by intentionally misleading or deceiving the PTO regarding inventorship; (3) the D'839 Patent is anticipated by the prior art; (4) the D'839 Patent is obvious based on the prior art; and (5) the D'839 Patent claims a primarily functional design.

Judgment is entered for Plaintiff in the amount of \$1,247,910.

An appropriate Order follows.